

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION MDL No. 2804
OPIATE LITIGATION Case No.
17-md-2804

This Document Relates to:
SALMONS v. PURDUE PHARMA LP, et al
MDL Case No. 1:18-op-45268

FLANAGAN v. PURDUE PHARMA LP, et al
MDL Case No. 1:18-op-45405
DOYLE v. PURDUE PHARMA, LP, et al
MDL Case No. 1:18-op-46327

Zoom Deposition of Lewis P. Rubin, M.D.
Washington, D.C.
September 10, 2020
10:05 a.m.

Reported by: Bonnie L. Russo
Job No. 4242152

1 Zoom Deposition of Lewis P. Rubin, M.D. held
2 at:

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7 1625 I Street, N.W.
8 Washington, D.C.
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C O N T E N T S

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MARKED QUESTION:

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P R O C E E D I N G S

(10:05 a.m.)

LEWIS P. RUBIN, M.D.,

being first duly sworn, to tell the truth, the whole truth and nothing but the truth, testified as follows:

EXAMINATION BY COUNSEL FOR PLAINTIFFS

BY MR. BILEK:

Q. Could you identify yourself for the record, please.

A. My name is Dr. Lewis P. Rubin.

Q. Dr. Rubin, this is my first Zoom deposition in my life which is probably your first as well I would imagine, and so don't be afraid if we have technical glitches that we will have to work through it and we're just going to try to do the best we can.

One of the things, because we are doing this and I would consider it a new format of a video deposition, I need to have some additional agreements from you.

1 During a pending question, please do
2 not check your phone or talk to counsel that is
3 there in the -- during the question until you
4 have answered the question and you can take a
5 break if you need to take a break.

6 Can we have that agreement?

7 A. Yes.

8 Q. As you understand, you are under
9 oath today under penalties of perjury just like
10 if you were in court even though we are not
11 formally together in a deposition. Do you
12 understand that?

13 A. Yes.

14 Q. And you're appearing here today
15 pursuant to a deposition notice.

16 Have you seen that deposition
17 notice?

18 A. Yes.

19 MR. BILEK: Could the court reporter
20 hand him Exhibit 1, please.

21 (Deposition Exhibit 1 was marked for
22 identification.)

1 MR. BILEK: Now, for the rest of
2 counsel, I have my paralegal who is forwarding
3 electronically all of the copies of the
4 deposition exhibits which you can get on the
5 break. There will be some delay on downloading
6 but she is going to try to do the best she can
7 to get those to you and as I say, hopefully,
8 this will all work both electronically, both on
9 the Veritext deposition -- I mean, the
10 deposition exhibits will appear as you need
11 them.

12 BY MR. BILEK:

13 Q. This deposition notice asks for
14 certain documents and one of the things that --
15 if you go -- I was provided an additional
16 report this week and it appears to be very
17 similar to the old report but we're going to go
18 through that, what the differences are, but
19 there's other things, subject to that new
20 report that was sent to me, is everything that
21 you relied on and identified in that report?

22 A. No.

1 MR. EHSAN: Object to the form.

2 BY MR. BILEK:

3 Q. Okay. What in addition have you
4 relied upon that is not in your report?

5 A. Two things. One is that I relied on
6 my clinical experience and expertise over four
7 decades that obviously is not in the report,
8 although it's alluded to, and the second is
9 that references in the report are merely meant
10 to be illustrative or citations on very
11 particular points. They're by no means
12 comprehensive. I did a much more extensive
13 review of the relevant literature.

14 Q. Well, Doctor, anything that you are
15 relying on, especially any studies or anything
16 like that that -- you have to produce that to
17 me. You can't hide the ball.

18 A. My understanding --

19 MR. EHSAN: Object to the form --
20 one second, Dr. Rubin. Object to the form.

21 Tom, the MCL is a Rule 26 compliant
22 MCL that we provided you.

1 THE WITNESS: That would have been
2 my answer.

3 BY MR. BILEK:

4 Q. Okay. Well, anything that supports
5 or you reviewed and relied on in connection
6 with your opinions have to be produced. I
7 mean, you can't -- you cannot say, okay, there
8 is some study that I -- I am relying on and not
9 produce it to me.

10 A. I'm sorry. You may have
11 misunderstood my previous response, or I may
12 have misstated it. I'm not sure. What I said
13 is the word "review." I did not say the word
14 "rely." I review literature on neonatal
15 abstinence syndrome and have since the 1980s.
16 What I relied on is in that MCL, I believe it's
17 called.

18 Q. Okay. Thank you, Doctor.

19 You -- this appears to be your only
20 expert opinion that you have ever rendered in
21 connection -- on behalf of a pharmaceutical
22 company; is that correct?

1 A. I believe that's correct.

2 Q. Why do you hesitate?

3 A. As I said, I think that it's
4 correct. I was scanning back in my mind.
5 There was at least one medical device suit but
6 that was not for the defendants.

7 Q. Okay. Who is paying you in this
8 case?

9 A. I submit a billing at the end of
10 every month on a website and then a check is
11 generated.

12 Q. Who does the check come from?

13 A. It's through an organization called
14 GLG.

15 Q. And who is GLG?

16 A. I don't recall what the names behind
17 the initials stand for. It's an organization
18 that seeks out experts for expert opinions in
19 different areas. In the past, I had rendered
20 or I had done consultations, none of them had
21 been legal or medical-legal. They contacted me
22 in reference to a legal case and that's how

1 things began.

2 Q. Okay. So is it like a group which
3 -- in which you solicit yourself to be
4 available as an expert? Is this what GLG is?

5 MR. EHSAN: Object to the form.

6 THE WITNESS: Largely, yes, with the
7 exception to the word "solicit." They
8 initially contacted me. I don't solicit myself
9 for consultations or opinions.

10 BY MR. BILEK:

11 Q. Is this the only case in which you
12 have worked through GLG?

13 A. The only -- yes. The only case,
14 yes.

15 Q. And the first time that GLG
16 contacted you was in connection with this case?

17 A. No. They have contacted me over the
18 past several years, maybe two, maybe three, in
19 reference to, would I be willing to do a phone
20 consultation about nonlegal subjects.

21 Typically, these are investors or other groups
22 who are interested in an aspect of the medical

1 or scientific market where people who want an
2 expert opinion about an aspect of medicine in a
3 totally nonlegal way.

4 Q. So have you worked with them on
5 these other matters in the past?

6 MR. EHSAN: Object to the form.

7 THE WITNESS: Let me try and be
8 clearer. They will send me a notice saying
9 they have a client who is interested in medical
10 devices used in neonatal ICUs, would I be
11 willing to speak with them, and then I either
12 respond yes or no and then a conference call is
13 arranged.

14 BY MR. BILEK:

15 Q. And there have been occasions in
16 which you have said yes, I assume.

17 A. I'm sorry. Could you repeat the
18 question.

19 Q. There have been occasions in which
20 you have said yes to other matters for GLG?

21 A. Yes.

22 Q. On how many occasions?

1 A. I don't recall. It comes up once
2 every several months.

3 Q. And these other matters, are you
4 working for pharmaceutical companies?

5 A. I'm pretty sure that none of these
6 -- no, in fact, I can say that definitively.
7 None of these have been on the behalf of
8 pharmaceutical companies.

9 Q. Okay. Getting back to GLG, who do
10 you -- who are GLG's clients in this case?

11 MR. EHSAN: Object to the form.
12 Outside the scope.

13 But if you know how to answer the
14 question, Dr. Rubin, by all means, go ahead.

15 THE WITNESS: My best answer to that
16 is that they referred me to attorneys at
17 O'Melveny. Beyond that, I have no knowledge.

18 BY MR. BILEK:

19 Q. Well, who does O'Melveny represent
20 in this case?

21 A. The case that I was asked to render
22 a report about is a case in which O'Melveny

1 attorneys are defending attorneys for -- I was
2 told two pharmaceutical companies.

3 Q. And what are those two
4 pharmaceutical companies?

5 A. What I had read is that they are
6 Johnson & Johnson and Janssen.

7 Q. Okay. And do you have any
8 understanding of what the role was for Johnson
9 & Johnson in connection with opioids?

10 MR. EHSAN: Object to the form.

11 THE WITNESS: No, that -- I mean,
12 no, specifically, in that, you know, I don't
13 have, you know, offhand recall of which
14 pharmaceutical companies make which opioids.
15 None of that has to do with what I was asked to
16 render a report about.

17 BY MR. BILEK:

18 Q. Well, you understand Johnson &
19 Johnson was involved with the manufacture of
20 opioids, correct?

21 A. My knowledge is what I just stated,
22 that they and a variety of other pharmaceutical

1 companies have manufactured synthetic opioids.

2 Q. And -- and Johnson & Johnson is
3 famous for their involvement with the super
4 poppy, right?

5 MR. EHSAN: Object to the form.

6 THE WITNESS: I've never heard that
7 expression.

8 BY MR. BILEK:

9 Q. You've never heard that?

10 A. No.

11 THE COURT REPORTER: Could you
12 repeat that expression too for me, "the
13 super" --

14 MR. BILEK: Super poppy.

15 THE COURT REPORTER: Super coffee?

16 THE WITNESS: Poppy.

17 MR. BILEK: Poppy.

18 BY MR. BILEK:

19 Q. But you understood Johnson & Johnson
20 does -- is involved with the manufacture of the
21 synthetic opioids?

22 A. Yes, I believe I have responded

1 twice to that.

2 Q. Okay. And then what is your
3 understanding what Janssen does in connection
4 with opioids?

5 A. No more or less than my knowledge
6 specifically of J&J.

7 Q. Now, you have to disclose conflict
8 of interest in various things, right?

9 MR. EHSAN: Object to the form.

10 THE WITNESS: I am sorry. Could you
11 repeat that question.

12 BY MR. BILEK:

13 Q. In connection with -- you have
14 obligations to various people to disclose
15 conflicts of interest; is that correct?

16 MR. EHSAN: Object to the form.

17 THE WITNESS: Could you better
18 define "various people"?

19 BY MR. BILEK:

20 Q. Anyone. Do you have any obligation
21 at all to disclose the conflict of interest?

22 MR. EHSAN: Object to the form.

1 THE WITNESS: When there is a
2 potential conflict of interest, I always
3 declare that.

4 BY MR. BILEK:

5 Q. Okay. Have you told anyone that you
6 are working on behalf of Johnson & Johnson and
7 Janssen?

8 A. Two-part answer. First part is no.
9 The second part is, I was asked to draft a
10 report and speak to attorneys at O'Melveny.
11 Fairly late in the process, I was given a
12 document that said that the -- the firms that
13 O'Melveny is representing are J&J and Janssen
14 so -- and I am not working directly for any
15 pharmaceutical company.

16 Q. So you say that you don't disclose
17 that you are working for any pharmaceutical
18 company because you are -- the money is being
19 funneled through O'Melveny and then through
20 your consulting group; is that correct?

21 MR. EHSAN: Object to the form.
22 Argumentative.

1 THE WITNESS: I really think that's
2 twisting things. You started off by asking me
3 if I declare conflicts of interest, to which I
4 applied -- replied, "I always declare conflicts
5 of interest." In the future, if something
6 comes up where this particular instance could
7 be perceived as a conflict of interest -- I
8 reiterate in the future, I certainly would do
9 so.

10 But I need to clarify one thing. I
11 was asked to draft a report about specific
12 aspects of neonatal abstinence syndrome. That
13 is the beginning and the end of my expert
14 opinion.

15 BY MR. BILEK:

16 Q. Got you. I understand. We're going
17 to get into your report. Don't worry about
18 that.

19 A. I'm not worried.

20 Q. I am asking you -- okay. What I'm
21 asking is this question: You understand that
22 you are getting paid by Johnson & Johnson and

1 Janssen, correct?

2 A. No. I don't know that for a fact.

3 Q. You don't know that for a fact?

4 A. No. That would be surmising on my
5 part.

6 Q. Has any lawyer at O'Melveny told you
7 that you are being retained into rendering
8 opinions on behalf of Johnson & Johnson and
9 Janssen?

10 MR. EHSAN: Objection.

11 Dr. Rubin, just be careful not to
12 discuss anything that is conversations between
13 attorneys and yourself. That's protected by
14 privilege, and I will instruct you not to
15 answer the question, but if you can answer
16 without divulging any attorney-client
17 communication, go ahead.

18 MR. BILEK: Wait a minute. This is
19 important because -- and it certainly -- he
20 does -- well, strike that.

21 BY MR. BILEK:

22 Q. Let's get down to the basis of it.

1 Are you represented by O'Melveny in
2 this case?

3 MR. EHSAN: Tom, are you -- you are
4 now asking him for a legal opinion. The simple
5 issue is he's already answered all your
6 questions. What are you trying to -- I think
7 your series of questions have a bunch of
8 implied language, and I don't want to have a
9 speaking discussion with you, but if you want
10 to ask the question, ask your questions, and
11 then take his answer.

12 MR. BILEK: I'm sorry. Sir, first
13 of all, we're going to have to call the special
14 master. You are getting involved -- your
15 speaking objection. He's heard the questions
16 that I have for him, and you can object to the
17 form of the question.

18 BY MR. BILEK:

19 Q. But going back, Dr. Rubin, are you
20 being represented by O'Melveny? Are they your
21 lawyers?

22 A. No.

1 MR. EHSAN: Object to the form.
2 Outside the scope. Calls for a legal opinion.

3 MR. BILEK: You're -- object to the
4 form.

5 BY MR. BILEK:

6 Q. But you can answer the question,
7 Dr. Rubin.

8 A. Well, I don't know the answer to
9 that. I -- to the extent to which as a layman
10 in terms of legalities that I'm aware in
11 providing a report and speaking at this
12 deposition, I represent myself. Beyond that, I
13 don't understand, you know, the question or its
14 implications.

15 Q. Well, let's go back now.

16 A. Okay.

17 Q. The issue of who is paying you. You
18 certainly have an understanding that you are
19 getting paid by Janssen and Johnson & Johnson,
20 correct?

21 A. No.

22 MR. EHSAN: Objection.

1 THE WITNESS: You have asked me that
2 before and I keep responding in the same way,
3 which is the truthful response. I am paid by
4 an organization that has a relationship for
5 this case with O'Melveny.

6 Beyond that -- and O'Melveny
7 attorneys are defending attorneys for these two
8 drug companies, I was told late in the process.
9 But it is purely speculation to me -- for me on
10 what the ultimate derivation of my fee is.

11 I need to reiterate. I was asked
12 something very specific, to provide my
13 expertise for this report and now to explain --
14 I presume to explain my report in the course of
15 this deposition. I am not representing per se
16 anybody aside from myself. I am rendering an
17 expert opinion.

18 BY MR. BILEK:

19 Q. Exactly. Now, the issue of when did
20 you -- when did you have an -- reach an
21 understanding that O'Melveny represented these
22 two drug companies?

1 MR. EHSAN: Object to the form.

2 THE WITNESS: Probably several
3 months ago.

4 BY MR. BILEK:

5 Q. February?

6 A. Excuse me?

7 MR. EHSAN: Object to the form.

8 BY MR. BILEK:

9 Q. Was it before or after you rendered
10 your report?

11 A. Mr. Bilek, I strive to be precise in
12 my answers. When I say "several months," that
13 is to the best precision that I can manage.

14 Q. And I was trying to see if I
15 could -- try to see if you recall whether it
16 was before your report or after your report?

17 A. That's a different question. I will
18 respond to that: After my report.

19 Q. Okay. And so you rendered your
20 opinion in this case -- I mean, I am just
21 trying to understand.

22 What was your understanding of why

1 you were rendering this report?

2 A. I was asked -- I was retained by --
3 indirectly by the firm O'Melveny in order to
4 render a report that covered specific aspects
5 of neonatal abstinence syndrome in three areas.
6 That's exactly what my report does.

7 Q. And you didn't care who was paying
8 you?

9 MR. EHSAN: Object to the form.
10 Argumentative.

11 THE WITNESS: Actually, I think that
12 is kind of demeaning.

13 BY MR. BILEK:

14 Q. We're going to get to some harder
15 issues here than that.

16 I am just trying to understand, when
17 you agreed to work for these people, you didn't
18 know who you were working for?

19 A. Who are "these people" who you refer
20 to?

21 Q. Johnson & Johnson and Janssen.

22 A. I am not working directly for

1 Johnson & Johnson or Janssen. I have rendered
2 an expert report. When you read my report,
3 which I'm sure you have, you will see that
4 there is no mention of any pharmaceutical
5 companies in it. I deal with neonatal
6 abstinence syndrome.

7 Q. Have you seen any -- have you seen
8 any literature or anything about the issue of
9 people being biased by the people that are
10 paying them?

11 MR. EHSAN: Object to the form.

12 BY MR. BILEK:

13 Q. Pharmaceutical companies have been
14 able to get favorable reports by paying money?

15 MR. EHSAN: Same objection.

16 THE WITNESS: I don't think I have,
17 but the implication clearly is that that
18 relates to me. I hold a standard for anything
19 in which I am consulted to the highest
20 peer-review standards that I adhere to in my
21 clinical practice and in my science. It's -- I
22 used the word before "demeaning." I think

1 that's turning out to be mild if you are
2 suggesting anything else in my case.

3 BY MR. BILEK:

4 Q. I'm not suggesting anything. I am
5 just here asking you questions, Doctor.

6 A. Not to my knowledge, is the response
7 to your last question.

8 Q. Okay. But you have not told anyone
9 that you are getting money from Janssen and
10 from Johnson & Johnson, correct?

11 MR. EHSAN: Object to the form.

12 THE WITNESS: Your question goes
13 back to grounds that we have been retreading
14 for the last, I think, 15 minutes. I have told
15 you where and how I get paid.

16 In terms of discussion of anything
17 about this case, aside from discussions with
18 attorneys at O'Melveny and discussions with you
19 today, I, of course, never would discuss
20 anything.

21 BY MR. BILEK:

22 Q. Okay. Going back to my Exhibit 1,

1 documents you are supposed to produce.

2 The -- you, on issue No. 5 were to
3 produce all billing records.

4 Do you see that?

5 A. May I ask where you are looking?

6 Oh, yes. I see it on Page 5. That
7 documentation as well as all the rest of the
8 documentation I am told has been provided.

9 Q. I have not received that, so if you
10 could have O'Melveny forward the billing
11 records.

12 Do you know approximately how much
13 you have billed in this case?

14 A. From its beginning in 2019 are you
15 asking?

16 Q. Yes.

17 A. Okay. When I last looked, it came
18 to somewhere between 60 and 70 hours.

19 Q. How much do you bill per hour?

20 A. \$600.

21 Q. So we are talking somewhere in the
22 area of 30, 40,000 you think?

1 A. Well, I would have to do the math
2 which requires a pencil or use of my phone.
3 You told me not to use my phone.

4 Q. Okay. When were you retained in
5 this case?

6 A. Sometime in 2019.

7 Q. Sometime in 2019. Was it only 2019,
8 late? Can you tell me more than that?

9 A. As I have tried to explain, I am
10 doing my best to give you the degree of
11 precision to each of your answers. If I knew
12 more precisely offhand in 2019, I would say so.
13 It would be several months at the most before
14 the date of my report.

15 Q. Okay. That's helpful. What were
16 they telling you that -- what was the purpose
17 of your retention?

18 MR. EHSAN: Object to the form.

19 THE WITNESS: You started to ask one
20 question and then went into another. Could you
21 repeat the question.

22 BY MR. BILEK:

1 Q. What is your understanding of the
2 purpose of your retention?

3 A. I was retained as someone who has
4 expertise, professional expertise and vast
5 experience in neonatal abstinence syndrome,
6 that being the reason I was asked to draft a
7 report that again covered three specific areas
8 about neonatal abstinence syndrome.

9 Q. Who do you work for right now?

10 A. Right now --

11 MR. EHSAN: Object to the form.

12 BY MR. BILEK:

13 Q. What hospital? What's your primary
14 job?

15 A. Okay. Two different questions.
16 Which one do you want me to answer? Who am I
17 working for right now is the first question.

18 Q. I have already talked about working
19 for O'Melveny in this case. What I am talking
20 about is what -- what's your -- what hospital
21 do you work for?

22 MR. EHSAN: Object to the form.

1 BY MR. BILEK:

2 Q. Or practice?

3 A. I practice at Georgetown University
4 Hospital.

5 Q. Okay. And are you employed there or
6 are you just -- that's where you -- explain
7 your relationship with Georgetown University
8 Hospital?

9 A. So I am employed. I am a professor
10 at Georgetown University Medical Center.

11 Q. Now at Georgetown, do you have to
12 disclose any of your outside consulting?

13 A. Offhand, I can't answer that with
14 precision beyond. I am required to declare any
15 outside consulting over a certain money
16 threshold. That's my best recollection.

17 Q. Okay. I've had my partner just pull
18 up the financial conflict of interest policy
19 for Georgetown University. Have you ever
20 looked at that?

21 A. I am not employed directly by
22 Georgetown University.

1 Q. And so are you saying that the --
2 are you doing a teaching for Georgetown?

3 A. I am employed by MedStar Georgetown
4 University Hospital. I have an appointment at
5 Georgetown University.

6 Q. So under your appointment at
7 Georgetown University, are you saying that your
8 financial conflict of interest policy doesn't
9 apply to you?

10 A. I never implied that.

11 MR. EHSAN: Object to the form.

12 THE WITNESS: I never implied that.

13 BY MR. BILEK:

14 Q. Okay. Does this financial conflict
15 of interest --

16 A. No. No. Let me finish my answer.
17 You are cutting me off. Let me finish my
18 answer.

19 My answer is that I had previously
20 stated that I conform to all conflict of
21 interest policies and I have at Georgetown
22 University.

1 Q. Have you disclosed to Georgetown
2 University the payments in this case?

3 A. No.

4 MR. EHSAN: Object to the form.

5 THE WITNESS: Because I had not
6 received -- I need to respond to your question.
7 It's a -- it's not a no. It's a no because.
8 It's a no because the last filing, which was
9 more than a year ago at Georgetown University
10 for my annual conflict of interest, predated
11 any payment in this case. I certainly will be
12 declaring it the next time I file my conflict
13 of interest form.

14 BY MR. BILEK:

15 Q. So are you saying that you have no
16 ongoing obligation to disclose conflict of
17 interest --

18 MR. EHSAN: Object to --

19 BY MR. BILEK:

20 Q. -- under the Georgetown University
21 policy?

22 MR. EHSAN: Object to the form.

1 THE WITNESS: I do do that on an
2 ongoing basis. However, the ongoing basis is
3 when I receive requests for updates. It's not
4 done on a day-to-day basis.

5 BY MR. BILEK:

6 Q. And so when do you get these
7 requests to update your disclosure of financial
8 conflict from Georgetown?

9 A. I'm sorry. You asked me when?

10 Q. Yeah. When.

11 MR. EHSAN: Same objection.

12 THE WITNESS: When I receive the
13 next one, I'll know. They are at least once a
14 year.

15 BY MR. BILEK:

16 Q. At least once a year?

17 A. Well, they are at least once every
18 calendar year.

19 Q. Have -- and you have been working on
20 this case for certainly almost a year now, and
21 you are saying that you have not received a
22 single request for conflict of interest from

1 Georgetown in that period of time?

2 MR. EHSAN: Object to the form.

3 THE WITNESS: We are going in
4 circles. Let me repeat. When I last received
5 a conflict of interest request from Georgetown
6 University Medical Center, I was -- I had not
7 yet received any payments on this case. Hence,
8 there was nothing for me to declare. Whenever
9 -- and it's probably going to be fairly soon, I
10 receive my next annual request for a conflict
11 of interest, I will continue to be thorough.
12 And by the way, it's potential conflicts of
13 interest.

14 BY MR. BILEK:

15 Q. And your conflict of interest form,
16 when you fill it out, who are you going to put
17 that you have a conflict of interest? What's
18 the conflict of interest? Is it O'Melveny, or
19 is it Janssen and Johnson & Johnson?

20 MR. EHSAN: Object to the form.

21 THE WITNESS: It's actually neither.
22 The conflict of interest form will ask if I

1 have received compensation by an entity --
2 compensation beyond whatever the threshold is,
3 this is certainly beyond the threshold, and I
4 will list that.

5 BY MR. BILEK:

6 Q. And what entity do you intend to put
7 on there?

8 A. I'm sorry. Could you repeat that.

9 Q. When you fill out your -- when you
10 disclose this to Georgetown, what entity are
11 you going to put down there?

12 MR. EHSAN: Object to the form.
13 Calls for speculation.

14 THE WITNESS: Well, since it hasn't
15 come up, I haven't decided it or haven't
16 thought about it. It's either going to be GLG
17 with parentheses O'Melveny, or it will say
18 O'Melveny.

19 BY MR. BILEK:

20 Q. I think I understand.

21 MR. EHSAN: Objection. Move to
22 strike.

1 BY MR. BILEK:

2 Q. The -- so the Georgetown conflict of
3 interest when I asked previously whether you
4 had, you know, entities that request, you know,
5 you to disclose conflict of interests, have we
6 now has established Georgetown does, is there
7 any other group that -- in which you have to
8 disclose conflict of interest?

9 MR. EHSAN: Object to the form.

10 THE WITNESS: Yes. Yes. I
11 previously answered that.

12 BY MR. BILEK:

13 Q. Which -- who else do you have to
14 disclose conflict of interest to?

15 A. As I previously answered, MedStar
16 Georgetown University Hospital.

17 Q. Now, other payments by
18 pharmaceutical companies, have you had any
19 other payment from pharmaceutical companies,
20 for example, buying you lunch or paying you for
21 seminars?

22 MR. EHSAN: Object to the form.

1 THE WITNESS: Two point -- two
2 prong, not prong. Two-part response. One is
3 that you are assuming I am paid by a
4 pharmaceutical company. I am paid by GLG.
5 They are paid by O'Melveny.

6 I will say for yet another time,
7 perhaps we can ask for the record to be read
8 back for future questions on this, I will say
9 that beyond that is speculation.

10 In terms of the second part, there
11 are national standards for physicians on what
12 they are and are not supposed to accept from
13 any pharma company, any commercial interest of
14 any kind, and I adhere scrupulously to those.

15 BY MR. BILEK:

16 Q. Okay. Have you received any money,
17 in whatever form, whether to go to seminars,
18 travel expenses, lunches? Have you received
19 any money from any pharmaceutical companies?

20 A. The latter two --

21 MR. EHSAN: Object to the form.

22 THE WITNESS: The latter two,

1 travel, lunches, are strictly prohibited. And
2 to detail my previous answer, sir, no.

3 BY MR. BILEK:

4 Q. Okay.

5 A. The former -- for --

6 Q. And --

7 A. You are cutting me off. The former
8 part of the question. Payment for -- could you
9 read back the first part of your question.

10 Q. I'm trying to find whether you have
11 had any payments from any pharmaceutical
12 company --

13 A. I'm --

14 Q. -- ever.

15 A. I am trying to answer.

16 Q. I am trying --

17 A. I am trying to answer your vague
18 questions with exactitude.

19 May I request that we have the first
20 part of your question read back.

21 (The record was read as requested.)

22 THE WITNESS: Okay. So the

1 operative words are "to go to seminars." I
2 have in the past attended scientific
3 conferences that have been sponsored by
4 commercial entities. Those are not for support
5 of any product or any device. Those are part
6 of my academic duties.

7 BY MR. BILEK:

8 Q. And what companies were sponsoring
9 those? What was your understanding?

10 A. So --

11 MR. EHSAN: Object to the form.

12 THE WITNESS: So the only one is
13 that I sit on an advisory board for Abbott
14 Nutrition. That advisory board pre-COVID would
15 have meetings. To attend those meetings, I
16 would -- Abbott Nutrition would sponsor the
17 members of the advisory board for their travel
18 to come out to attend that meeting.

19 BY MR. BILEK:

20 Q. And so they would pay you for that?

21 A. Yes.

22 MR. EHSAN: Object to the form.

1 BY MR. BILEK:

2 Q. Have you received any -- have you
3 received any other compensation from Abbott in
4 connection with you being on the advisory
5 board?

6 A. Not that I recall, no.

7 Q. Okay. Now, have you -- on any other
8 advisory boards for any other company?

9 A. Not currently.

10 Q. In the past?

11 A. In the past, I have been an advisor
12 to at least two medical device companies.

13 Q. What were those two companies?

14 A. One is no longer in business. I
15 believe their name was Life Technologies. And
16 the other one, I don't recall the name. In
17 both cases, I really should clarify. These
18 were scientific advisory companies -- excuse
19 me, scientific advisory functions.

20 Q. Well, were you receiving any
21 compensation in connection with those or
22 reimbursement of expenses?

1 A. It was so long ago I don't recall.
2 Certainly no compensation aside from perhaps
3 coverage to attend a meeting.

4 Q. Let's move to Plaintiff's Exhibit 2.
5 I'm going to hand you Plaintiff's Exhibit 2.

6 (Deposition Exhibit 2 was marked for
7 identification.)

8 BY MR. BILEK:

9 Q. Okay. I'm going to represent to
10 you, this is the report that you first -- that
11 I first received back in February.

12 Do -- can you identify this document
13 for me?

14 A. Well, I didn't receive this report
15 in February. I wrote this report.

16 Q. I'm not asking you whether I
17 received it in February. What I am saying is,
18 can you identify Exhibit 2?

19 A. Yes. I am just trying to answer the
20 specific questions.

21 Yes. This is my report.

22 Q. Okay. And I then --

1 MR. BILEK: Could the court reporter
2 hand him Exhibit 3, please.

3 (Deposition Exhibit 3 was marked for
4 identification.)

5 BY MR. BILEK:

6 Q. This is the report that I just
7 received this week.

8 Can you identify Exhibit 3?

9 A. Yes --

10 MR. EHSAN: I'm going to object to
11 the extent you are characterizing it as a new
12 report that you received.

13 Go ahead, Dr. Rubin.

14 THE WITNESS: What I am seeing is,
15 glancing through it, exhibit -- Exhibit 2's
16 report and Exhibit 3's report appear to be
17 identical. I only submitted one report.

18 BY MR. BILEK:

19 Q. Okay. Well, that's what I am
20 getting at. This report -- have you made any
21 changes to Exhibit 2?

22 MR. EHSAN: Object to the form.

1 THE WITNESS: If, as I understand
2 it, you are asking me if I made any changes or
3 amendments to the report that I first
4 submitted, the answer to that is no.

5 BY MR. BILEK:

6 Q. Okay. Well, that makes things
7 simpler.

8 A. I hope so.

9 Q. Going back to Exhibit 2, the first
10 question I have is you marked this document as
11 confidential. Why?

12 MR. EHSAN: Object to the form.
13 Outside the scope.

14 THE WITNESS: I submitted the
15 report, that addition to it was not from me.
16 It certainly is a confidential report.

17 BY MR. BILEK:

18 Q. Why is it a confidential report?

19 A. From my point of view, it's
20 confidential because as I previously stated
21 towards the beginning, I haven't discussed this
22 or shared this outside of the context of

1 providing this to the attorneys and discussing
2 it with you here today. To me, that means
3 confidential. Subject to protective order is
4 not my language. I don't know what that means.

5 Q. Okay. On the confidential -- was it
6 you that put "confidential" on this report?

7 A. I previously answered that.

8 Q. I didn't understand your answer
9 then.

10 Did you or did you not put
11 "confidential" on it?

12 A. For a second time, no.

13 Q. Okay. So -- but you do consider
14 this report confidential?

15 A. For my definition of confidential,
16 everything about this pending legal case is, of
17 course, confidential. It's a legal case.

18 Q. Why?

19 A. That's my understanding of pending
20 legal cases.

21 Q. You think pending legal cases are
22 confidential?

1 A. This is getting way --

2 MR. EHSAN: Object to the form.

3 Argumentative.

4 Dr. Rubin, just give me a second to
5 object.

6 THE WITNESS: Yeah. Sure. Sure.

7 Sorry.

8 MR. EHSAN: Object to the form.

9 Argumentative.

10 THE WITNESS: This is getting way
11 beyond --

12 MR. BILEK: I am getting really
13 tired of --

14 THE WITNESS: Sorry.

15 MR. BILEK: -- your improper
16 objections. And I am ready to get Colin on the
17 phone right now because -- just follow the
18 rules.

19 MR. EHSAN: There is a body of
20 federal case law that says just objecting to
21 form does not give the questioner sufficient
22 information to correct his or her question in

1 order to ask an admissible question to be
2 submitted at trial.

3 I am trying to do you a favor here.
4 If you don't want me to do that and that's what
5 you want and you just want me to object to the
6 form, I am happy to do that. But I don't want
7 you to complain later saying you didn't give me
8 an opportunity to correct my question as
9 necessary.

10 MR. BILEK: Yes. I -- I do not need
11 any legal help from you. So I would prefer you
12 to follow the rule. Thank you. I will let you
13 know if --

14 MR. EHSAN: If you'd like me to just
15 object to the form and nothing else, that's
16 fine.

17 MR. BILEK: Thank you.

18 BY MR. BILEK:

19 Q. Dr. Rubin, going back to your
20 understanding of why this report should be kept
21 confidential.

22 Is it just because you are saying

1 that legal cases should be confidential?

2 MR. EHSAN: Object to the form.

3 THE WITNESS: You are getting way
4 outside of any area of expertise I have. My
5 expertise relevant to this case is in neonatal
6 abstinence syndrome. It is marked
7 confidential. I did not mark it confidential.
8 That's kind of the end of my knowledge about
9 this.

10 BY MR. BILEK:

11 Q. But you are -- you have been
12 affirmatively keeping this confidential,
13 correct?

14 A. In the sense as you, towards the
15 beginning of the deposition, had asked me. You
16 asked, have I discussed this with anybody, and
17 I have responded now several times. I have
18 only discussed this with O'Melveny attorneys
19 and with you. That is a definition of keeping
20 confidentiality.

21 Q. Okay. Going to your expertise in
22 this case --

1 A. Thank you.

2 Q. -- how many articles have you
3 published on opioids?

4 MR. EHSAN: Object to the form.

5 THE WITNESS: Several. That's the
6 best I can characterize the number, meaning a
7 few that deal with the use of opioid therapy in
8 babies hospitalized in a neonatal intensive
9 care unit.

10 BY MR. BILEK:

11 Q. Let's go to your report, and you can
12 -- I think you have your list of publications
13 on here. Which articles --

14 A. My list of publications is in my CV.
15 Is that where you want me to go?

16 Q. I think it's attached to your report
17 here, if you will look.

18 A. No. I know. You said "in my
19 report." Attached to my report, I will look.
20 Yes.

21 Q. Doctor, I mean, this is going to be
22 a long day. But this report is all in one

1 thing, and it's Exhibit A. Don't you consider,
2 like, Exhibit A part of your report?

3 MR. EHSAN: Object to the form.

4 THE WITNESS: I have no knowledge of
5 how exhibits are designated legally. Would you
6 like me to go to part of my CV right now?

7 BY MR. BILEK:

8 Q. Yes, sir.

9 A. And what would you like me to look
10 at?

11 Q. Which articles you published that
12 concerned opioids.

13 MR. EHSAN: Object to the form.

14 THE WITNESS: You will need to give
15 me several minutes. There are a few articles.

16 BY MR. BILEK:

17 Q. I think we have a lot -- a lot of
18 time together.

19 A. Excuse me? I'm sorry.

20 Q. I think we're going to have a lot of
21 time together so --

22 A. We're going to be heading to a lunch

1 break for sure.

2 Okay. So the most relevant one is
3 Reference No. 20 appearing on Page 20.

4 Q. Okay. You are saying that involves
5 opioids?

6 A. Yes. It says so right in the title.

7 Q. Okay. 20. What other ones have you
8 written?

9 A. To my recollection, that is the
10 major one or that is the one that has opioids
11 were -- as it states in that article,
12 narcotics, as the principal part of the
13 article.

14 As you can see, there are numerous
15 articles that deal with neonatal intensive care
16 and aspects of it. Off the top of my head, I
17 couldn't say which ones include the use of
18 opioids as therapies in babies.

19 Q. What I am looking for, Doctor, is
20 anything that has to do with opioids causing
21 NAS.

22 Have you done any articles on that?

1 MR. EHSAN: Object to the form.

2 THE WITNESS: Thank you for asking
3 me the direct question. No, I don't recall
4 publishing anything in peer-reviewed literature
5 about NAS. The Reference No. 20 probably
6 refers -- I would have to go back and reread
7 it. It's from 1998, but it probably refers to
8 some of the consequences of narcotics or
9 opioids prescribed for babies in neonatal
10 intensive care units, but it does not deal
11 specifically with NAS.

12 BY MR. BILEK:

13 Q. Okay. So there is no peer-reviewed
14 study that you have written on NAS being caused
15 by opioids, correct?

16 MR. EHSAN: Object to the form.

17 THE WITNESS: Aside from my
18 qualification about Reference 20, that is
19 correct.

20 BY MR. BILEK:

21 Q. Okay. You have published no study
22 on use of opioids in pregnant women?

1 A. That's correct. I'm a
2 neonatologist, not an obstetrician.

3 Q. You have not published any studies
4 on the clinical factors related to opioid
5 tolerance dependence or withdrawal?

6 A. Not to my recollection.

7 MR. EHSAN: Object to the form.

8 THE WITNESS: Not to my
9 recollection.

10 BY MR. BILEK:

11 Q. You have published no studies on
12 mechanisms associated with opioids, analgesia
13 tolerance or withdrawal?

14 A. With the exception of my need to
15 reread especially Reference 20, not to my
16 recollection. Although, you know, in different
17 review articles, that may or may not have come
18 up.

19 Q. What article?

20 MR. EHSAN: Object to the form.

21 THE WITNESS: Basically in any
22 review article that discusses neonatal

1 intensive care.

2 BY MR. BILEK:

3 Q. You have done no studies on the
4 development in the fetal and neonatal brain
5 with or without exposure to opioids?

6 MR. EHSAN: Object to the form.

7 THE WITNESS: I do studies on the
8 development of brain not in relationship in my
9 own research to the question of opioids per se.

10 BY MR. BILEK:

11 Q. You don't -- have done no studies on
12 the neurodevelopment outcome following prenatal
13 opioid exposure?

14 A. Myself? No.

15 Q. Now, you have worked with Dr. Anand
16 in the past, right?

17 A. By "worked with," he and I
18 overlapped in terms of some of our postgraduate
19 medical training, and we have, on and off,
20 known each other in the last several decades
21 although not worked directly with each other
22 since the 1980s.

1 Q. You would agree that Dr. Anand is
2 qualified to render expert opinion on NAS?

3 MR. EHSAN: Object to the form.

4 THE WITNESS: Well, I'm not
5 qualified to say in any kind of legal sense
6 obviously who is or is not qualified as an
7 expert in NAS. The only way I have to respond
8 to that question is that Dr. Anand is certainly
9 an expert on the use of opiates and opioids as
10 a treatment in newborns up through older
11 children.

12 In terms of experience with NAS, to
13 my knowledge, he doesn't deal with newborns
14 with neonatal abstinence syndrome since his
15 pediatric residency training in the 1980s.

16 BY MR. BILEK:

17 Q. Have you read his deposition, sir?

18 A. No.

19 Q. Have you read his report?

20 A. Yes.

21 Q. Have you seen what articles he has
22 published on neonatal abstinence syndrome?

1 A. I don't know about comprehensively,
2 but generally, yes.

3 Q. What is your understanding?

4 A. That he has published articles, some
5 of which relate in part to neonatal abstinence
6 syndrome.

7 Q. And do you consider yourself an
8 expert on neonatal abstinence syndrome?

9 A. I think by virtue of the following
10 reasons, I do have expertise. Those reasons
11 are that I have several decades of experience
12 taking care of possibly in the hundreds of
13 babies with NAS. I have served as the director
14 of newborn services of neonatal intensive care
15 and so been involved with setting
16 hospital-based standards about evaluation and
17 treatment, and I was the co-chair for several
18 years in the State of Florida of a statewide
19 initiative about neonatal abstinence syndrome.
20 So in those ways, yes.

21 Q. What was the initiative in Florida
22 that you were in charge of or involved in?

1 MR. EHSAN: Object to the form.

2 THE WITNESS: It's listed in my CV.

3 I was co-chair of an initiative led by the
4 Florida chapter of the March of Dimes and a
5 Florida organization called, not Healthy Start,
6 but something similar that provided services
7 for women and children. And this was a
8 multi-organizational task force to work --
9 excuse me, to work with the government of
10 Florida, the state government, at a time when
11 there had been a significant rise in the number
12 of babies with neonatal abstinence syndrome.

13 BY MR. BILEK:

14 Q. And was there an initiative
15 undertaken?

16 A. Could you repeat the question.

17 MR. EHSAN: Object to the form.

18 BY MR. BILEK:

19 Q. Did that -- what was the result?

20 A. We had made recommendations to the
21 state attorney general and also held seminars
22 with different law enforcement and mental

1 health providers throughout the state.

2 Q. What recommendations do you recall
3 them making?

4 A. So we generated no report. We
5 educated the parties that I just mentioned
6 about the -- what seemed to be the immediate
7 causes of the uptake in neonatal abstinence
8 syndrome and also began to work with hospitals
9 about trying to decrease some of the variation
10 in treatment for NAS.

11 Q. What was the recommendation as far
12 as trying to reduce the number of the
13 occurrences of NAS?

14 A. I'm sorry. Could you read back my
15 previous answer.

16 (The record was read as requested.)

17 THE WITNESS: Could you read back,
18 I'm sorry, Mr. --

19 MR. BILEK: Bilek.

20 THE WITNESS: Sorry. His question
21 to me.

22 THE COURT REPORTER: The question

1 that I just read the answer to?

2 THE WITNESS: No. No. The question
3 that he just asked me after that.

4 THE COURT REPORTER: The one he just
5 asked.

6 THE WITNESS: Thank you.

7 (The record was read as requested.)

8 THE WITNESS: Thank you. With Zoom,
9 I know it's difficult on all of us. I just
10 wanted to make sure that I heard your question
11 correctly and my previous response.

12 So I would reiterate what is in that
13 response. We make no recommendations about
14 reducing the causes of neonatal abstinence
15 syndrome. We educated public officials and
16 others about essentially the epidemiology of
17 it.

18 BY MR. BILEK:

19 Q. Okay. What was the epidemiology of
20 NAS that you were educating them?

21 MR. EHSAN: Object to the form.

22 THE WITNESS: We had discovered that

1 at that time in several parts of Florida, that
2 there were -- there was, you know, what is
3 commonly called diversion of prescription-grade
4 medications, and there was also a large illicit
5 market in those medications. Yes.

6 BY MR. BILEK:

7 Q. Well, was -- the issue was on the
8 NAS was -- what one of the causes that you were
9 opining was that there were -- were
10 prescriptions or one of the causes of the NAS
11 that were being diverted?

12 MR. EHSAN: Object to the form.

13 THE WITNESS: That was, I'm sorry,
14 too complicated of a question for me to parse.
15 Could you repeat it, please.

16 BY MR. BILEK:

17 Q. I will restate it.

18 A. Thank you.

19 Q. Was -- what are the causes of the
20 uptick in the NAS in Florida? Was one of the
21 causes that that -- that prescriptions were
22 being diverted?

1 MR. EHSAN: Object to the form.

2 THE WITNESS: The causes of NAS are
3 many. At that time, we had noted, as was noted
4 by law enforcement, that there was an
5 increasing number of what are commonly called
6 pill mills where people would go in without an
7 examination or any kind of relationship with
8 either physician, sometimes with a pharmacist,
9 they would be given a script for an opioid.
10 Then they would go down the road and do that
11 again and do that several times. That's what I
12 meant by diversion.

13 There also was -- it seemed to be a
14 large black market in synthetic opioids.
15 That's over the context of, you know, a
16 continuing use of other illicit drugs, you
17 know, including heroin and especially
18 nonopioids.

19 BY MR. BILEK:

20 Q. What I am asking is, that the fact
21 was that the diversionary market, as you called
22 it, of prescriptions was one of the causes of

1 the uptick in NAS in Florida?

2 MR. EHSAN: Object to the form.

3 THE WITNESS: The use of opiates, of
4 certain opiates by pregnant women, where those
5 opiates were obtained illicitly was, yes, a
6 cause.

7 BY MR. BILEK:

8 Q. And a cause was the prescription,
9 correct?

10 MR. EHSAN: Object to the form.

11 THE WITNESS: When you say
12 "prescription," do you mean drugs that are
13 prescription drugs, meaning that they require a
14 prescription, or are you referring to
15 prescriptions written?

16 BY MR. BILEK:

17 Q. Prescriptions written. The
18 prescriptions -- the writing of the
19 prescription, those prescriptions whether they
20 are being diverted through the pill mills,
21 whatever they were doing in your words, that
22 was one of the reasons that we had an uptick of

1 NAS in Florida.

2 MR. EHSAN: Object to the form.

3 THE WITNESS: A reason was that
4 there were, as I previously referred to them,
5 pill mills which were certain physicians who
6 were not adhering to standards of practice or
7 ethics, medical ethics, who then were cracked
8 down upon in an initiative that happened a year
9 or two later in the State of Florida, basically
10 with licenses being taken away and with civil
11 and criminal proceedings as I recall against,
12 you know, unscrupulous providers.

13 BY MR. BILEK:

14 Q. Well, I mean, there is no dispute
15 that the use of opioids by a pregnant woman can
16 cause NAS.

17 A. It is one of the causes of NAS as it
18 is defined.

19 Q. And the use of the opioid, one of
20 the manners in which that the -- she, the
21 pregnant woman, could obtain the opioid is
22 through a prescription, correct?

1 MR. EHSAN: Object to the form.

2 THE WITNESS: So the accurate answer
3 to that is that pregnant women, like virtually
4 everybody else, a pregnant woman may have a
5 medical condition that warrants prescription of
6 opioids. In that sense, yes.

7 In the second sense, the other
8 condition is that there are women who are using
9 opiates, might be heroin, it might be some
10 synthetic opioid, and they are using that
11 recreationally and also being exposed to
12 polypharmacy and all of the, you know, the
13 other attendant factors.

14 But some of these women, and we hope
15 more of these pregnant women during the
16 pregnancy come into an opioid maintenance
17 program in which they do get a prescription for
18 an opioid, it's typically one of two, and the
19 reasons for that obviously are to keep them
20 from the dangers of drug seeking behavior or
21 the dangers of withdrawing during pregnancy.

22 That's a longer answer to your

1 question, but I'm sorry, I felt it was a bit
2 vague, and I needed to qualify. There are
3 prescriptions and there are prescriptions.

4 BY MR. BILEK:

5 Q. I understand. My point is, is that
6 the prescription would be -- when a woman is
7 taking a prescribed opioid and she has a child
8 that is born with NAS, that prescription would
9 be a cause of the NAS in the child.

10 MR. EHSAN: Object to the form.

11 THE WITNESS: Yes. With the
12 qualifier that the two main reasons for
13 prescribing opiates to women in the latter part
14 of pregnancy are either they have some medical
15 condition that has required or like now
16 requires opioids, or they have been essentially
17 hooked to opioids on, you know, illicitly and
18 are coming into a treatment program.

19 In both cases, yes, the proximate
20 cause of the NAS, perhaps you could say is the
21 fact that the prescription was written, but the
22 real cause is that this was required because of

1 earlier events often preceding the pregnancy.

2 BY MR. BILEK:

3 Q. Now, going back to Dr. Anand, you
4 have relied on his expertise in the past,
5 correct?

6 MR. EHSAN: Object to the form.

7 THE WITNESS: I certainly admire his
8 expertise and find it useful in specific areas.

9 BY MR. BILEK:

10 Q. And what are those areas?

11 A. Those areas have been the importance
12 of providing analgesia, meaning pain control,
13 to avoid physical and other stresses during
14 human development after birth.

15 Q. And you -- have you ever cited to
16 his published work?

17 A. I'm sorry. Zoom. Could you repeat
18 the question.

19 Q. In any of your articles, have you
20 ever cited to Dr. Anand?

21 A. I don't recall.

22 Q. But it's certainly possible,

1 correct?

2 A. Lots of things are possible. I
3 don't recall if I cited him. I certainly don't
4 know if he cited me.

5 Q. Okay.

6 MR. EHSAN: Tom, I don't mean to
7 interrupt your questioning, but if there is a
8 place that's a natural break point to take a
9 break, just let me know.

10 MR. BILEK: Okay. We will take a
11 break right here.

12 (A short recess was taken.)

13 BY MR. BILEK:

14 Q. I have a few clean-up questions on
15 stuff we did before.

16 Have you reviewed any of the reports
17 of the other defense experts in this case?

18 A. No.

19 Q. Have you reviewed any depositions at
20 all in this case?

21 A. No.

22 Q. Do you think there is an opioid

1 crisis in this country now?

2 MR. EHSAN: Object to the form.

3 THE WITNESS: Do I think there is an
4 opioid crisis? I -- frankly, my opinion is
5 that there is an increasing crisis in terms of
6 social inequities and an increase in drug use
7 as part of that.

8 BY MR. BILEK:

9 Q. And part of the -- we will get to
10 your opinions on poverty and social inequality,
11 but my question is: Is opioids part of the
12 problem?

13 MR. EHSAN: Object to the form.

14 THE WITNESS: I'm not sure -- I
15 don't think I know what you mean by "part of
16 the problem." Part of which problem?

17 BY MR. BILEK:

18 Q. I am trying to get at -- I mean, as
19 you -- are you aware of whether President Trump
20 signed an executive order saying there was an
21 opioid crisis in this country?

22 A. I must say that I -- or I will say

1 that for my own mental health, I don't pay as
2 much attention to what Mr. Trump says or does
3 as I have for previous presidents.

4 Q. Agreed. There is one thing -- we
5 may not agree on anything else today, but we
6 will agree on that.

7 My point is though that there has
8 been a rising use of opioids by people in the
9 last 20 years.

10 MR. EHSAN: Object to the form.

11 THE WITNESS: So my firsthand
12 knowledge of neonatal abstinence syndrome which
13 is a -- in part, a reflection, and part of that
14 is that in the time I have been practicing
15 medicine, I saw an increases in drug use in the
16 1980s. I saw some again in the 1990s, and I
17 have seen some again during the 21st Century.

18 BY MR. BILEK:

19 Q. And part of that increase and a big
20 part of that increased drug use is opioid use,
21 correct?

22 MR. EHSAN: Object to the form.

1 THE WITNESS: Opioids being defined
2 as natural and synthetic drugs of that class in
3 that broad category, yes.

4 BY MR. BILEK:

5 Q. And would you agree that part of
6 that cause of the increased abuse of opioids is
7 in part due to the increased prescriptions
8 written for opioids?

9 MR. EHSAN: Object to the form.

10 THE WITNESS: My clinical experience
11 is, of course, entirely with pregnant women and
12 their babies and in those instances, I can't
13 think of an instance that would fulfill the
14 criteria of your question.

15 BY MR. BILEK:

16 Q. Well, do you know whether -- there
17 has been studies on how many women have a
18 prescription for opioids during pregnancy.

19 Have you seen any of that evidence?

20 A. I have --

21 MR. EHSAN: Object to the form.

22 THE WITNESS: I have seen studies

1 that look at aspects of that, yes.

2 BY MR. BILEK:

3 Q. And that in the last 20 years, that
4 there has been a huge increase in the number of
5 women that have been given prescriptions for
6 opioids during pregnancy, correct?

7 MR. EHSAN: Object to the form.

8 THE WITNESS: The only women whom
9 I'm aware of who during pregnancy are written
10 prescriptions for opioids are women in one of
11 the two classes that I previously mentioned,
12 specifically women who have had opioids
13 prescribed because of underlying medical
14 conditions and so that needs to be continued in
15 pregnancy, and women who were illicitly taking
16 opioids and fortunately decided to go into a
17 treatment program and in that context were
18 prescribed opioids.

19 BY MR. BILEK:

20 Q. Do you think that part of the
21 increased use of opioids is due to increased
22 prescriptions being written for opioids?

1 MR. EHSAN: Object to the form.

2 THE WITNESS: I have no immediate
3 knowledge of that professionally or otherwise.

4 BY MR. BILEK:

5 Q. Are you aware of any governments
6 trying to limit or reduce the rate of
7 prescriptions for opioids?

8 MR. EHSAN: Object to the form.

9 THE WITNESS: I'm aware of
10 initiatives, I don't recall if they are by
11 governments, to encourage good practices with
12 prescription of pain meds.

13 BY MR. BILEK:

14 Q. And one of the good practices is to
15 reduce the number of prescriptions written for
16 pain meds, correct?

17 A. Again, I --

18 MR. EHSAN: Object to the form.

19 THE WITNESS: I have no immediate
20 knowledge of that since I'm not a pain med
21 physician.

22 BY MR. BILEK:

1 Q. Well, in Florida, did you guys come
2 to any recommendations orally that the use of
3 prescriptions for opioids should be reduced?

4 MR. EHSAN: Object to the form.

5 THE WITNESS: No. Again, as I had
6 previously explained, we, along with several
7 law enforcement agencies, educated people on
8 the occurrence of unscrupulous, rare, but
9 unscrupulous practitioners who were prescribing
10 opioids to people who would walk into these
11 pill mills.

12 BY MR. BILEK:

13 Q. So let's maybe go at it another way.
14 Do you have any opinion of whether
15 or not we should reduce the number of opioid
16 prescriptions that are being written in this
17 country?

18 MR. EHSAN: Object to the form.

19 THE WITNESS: I really can only
20 speak to my practice which is that I strive to
21 prescribe what is necessary and durations for
22 which it's necessary.

1 BY MR. BILEK:

2 Q. Well, so you have no opinion one way
3 or the other, is it fair to say, on whether
4 prescriptions for opioids should be reduced?

5 MR. EHSAN: Object to the form.

6 THE WITNESS: I think appropriate
7 pain control for people is very important. I
8 think physicians should adhere to good
9 practices. That's -- beyond that, it's --
10 beyond that, it's kind of out of my wheelhouse.

11 BY MR. BILEK:

12 Q. So the issue of -- well, should --
13 should -- do you have any opinion whether we
14 should try to reduce the number of children
15 being born with NAS?

16 A. I'm sorry babies are born with NAS,
17 of course. We treat it very appropriately when
18 it happens. Some of the cases of NAS are not
19 preventable in the sense that there are very
20 valid reasons for prescribing opioids to some
21 individuals during pregnancy. So we can't
22 eliminate NAS that way. It would be too

1 dangerous. I wish that there was less illicit
2 drug taking in the United States.

3 Q. Well, do you wish that there were
4 less opioid prescriptions given to pregnant
5 women?

6 A. Not necessarily, because to my
7 knowledge, speaking with practice in several
8 parts of the U.S. over four decades,
9 obstetricians prescribe, again, to my
10 knowledge, my experience, obstetricians
11 prescribe opioids to pregnant women for very
12 specific reasons.

13 Q. Do you know how many states are
14 passing laws to limit the writing of
15 prescriptions to pregnant women?

16 A. No.

17 Q. Would that -- the fact that there
18 are many states that are passing laws to limit
19 the number of prescriptions being written to
20 women, would that make any difference to your
21 opinion?

22 MR. EHSAN: Object to the form.

1 THE WITNESS: Well, I don't think
2 the question you are posing is entirely an
3 accurate statement for the following reason:
4 To my knowledge, states and state medical
5 boards in a variety of states have enacted
6 registries in order to be able to track
7 unscrupulous physicians who are not adhering to
8 appropriate medical practice and, you know,
9 writing prescriptions for opioids for not good
10 reasons.

11 That is something that's
12 substantively different from what you are
13 stating. And having those registries and
14 identifying those few physicians is very
15 important.

16 BY MR. BILEK:

17 Q. Well, what about laws being passed
18 just to limit the time duration of
19 prescriptions for opioids and then the
20 requirement on those prescriptions. Are you
21 aware of any -- any of those laws?

22 MR. EHSAN: Object to the form.

1 THE WITNESS: I'm not specifically
2 aware of laws. I am aware that aspects of both
3 of those things are part of good medical
4 practice.

5 BY MR. BILEK:

6 Q. What, reducing the amount of
7 prescriptions, what two things?

8 A. No. That's not what you said, sir.
9 What you said, we could have it read back, but
10 what you asked me about are the durations and
11 something similar.

12 Q. Okay.

13 A. That's good practice. You don't
14 give people a year's supply of something.

15 Q. So one of the things that you think
16 -- that as far as prescriptions, is trying to
17 -- in an appropriate practice would be to try
18 to limit the duration of the prescriptions for
19 pain medications?

20 A. Okay. I again apologize --

21 MR. EHSAN: Object to the form.

22 THE WITNESS: Sorry. I again

1 apologize. Part of that is Zoom getting you
2 garbled and part of that is I think your
3 question wound a little bit. Could you repeat
4 it for me, please.

5 BY MR. BILEK:

6 Q. Should -- in trying to reduce the
7 number of NAS occurrences, one of the measures
8 should be is to reduce the level of -- or not
9 the level, the duration of prescriptions for
10 opioids.

11 MR. EHSAN: Object to the form.

12 THE WITNESS: That's a question that
13 frankly posits something that is not based in
14 reality. Medical reality is that legitimate
15 prescribing of opioids for pregnant women is
16 done for specific purposes and for specific
17 durations. In terms of duration, what one does
18 not want to do is to withdraw a woman during
19 pregnancy for her sake and for the baby's sake
20 and there are very specific recommendations
21 from the American College of obstetricians and
22 -- Obstetrics and Gynecology that say, don't do

1 that.

2 BY MR. BILEK:

3 Q. Well, the appropriateness -- are you
4 an expert on the issue of the appropriateness
5 of withdrawing from opioids by a pregnant
6 woman?

7 A. Yes, in the following sense. As an
8 obstetrician, I cannot speak to individual
9 instances of standards of care, but I can do
10 two of the following things: One is that I can
11 and I have familiarized myself throughout my
12 career with recommendations for the appropriate
13 and good care of women during pregnancy and
14 that includes drug prescribing, and the second
15 is that, I am a neonatologist, so I am dealing
16 with patients who don't have their entire lives
17 starting at the moment of birth but have an in
18 utero history, and like some other, but not
19 like most other neonatologists, I also have a
20 fairly extensive background in fetal
21 physiology, fetal management, fetal diagnosis
22 working with other specialists including

1 obstetricians.

2 So in that sense, I am extremely
3 confident when I give you the expert opinion
4 that withdrawing a mom during pregnancy is a
5 no-no for the mom and for the fetus.

6 Q. The -- what is the basis of your
7 opinion on that?

8 A. A whole lot of physiology and
9 clinical experience but most pertinent, the
10 American College of Obstetrics and Gynecology
11 posts updates on clinical care and they in
12 effect are a standard of practice for
13 obstetrics.

14 Q. Have you ever prescribed any opioids
15 to a pregnant woman?

16 A. Since medical school, I have never
17 prescribed any drug to a pregnant woman.

18 Q. Have you ever recommended to any
19 obstetrician -- I mean, to any -- any doctor to
20 prescribe an opioid to a pregnant woman?

21 A. Yes.

22 MR. EHSAN: Object to the form.

1 BY MR. BILEK:

2 Q. When?

3 A. Quite a few times in the following
4 context. Because I do fetal consultations,
5 because I have led fetal diagnoses and
6 management programs in several institutions, I
7 work collaboratively with obstetricians and
8 meet with pregnant women, some of whom are
9 taking opioids and we discuss management, the
10 care providers. We all discuss appropriate
11 management.

12 Q. And how many occasions have you done
13 that?

14 A. Sorry. My delay was thinking about
15 frequency over a long time. Minimally, several
16 dozen times.

17 Q. And you -- were you recommending
18 that the opioids be continued?

19 A. My role has been looking at it from
20 the perspective of the fetus, and certainly I
21 adhere to the appropriate and standard of
22 practice which is not to withdraw a pregnant

1 woman, instead to provide maintenance.

2 Q. Does the maintenance stay at the
3 same rate or do you try to reduce the dose?

4 A. Well, that depends on the situation
5 of course. Everything is individualized and
6 discussions of exact dose of medicine and
7 obstetrician's preference for one versus
8 another, those reside with the obstetrician who
9 is actually writing the prescription.

10 The general principle is enough but
11 not too much as in all things.

12 Q. What is enough or not too much?

13 A. Enough to prevent withdrawal.

14 Q. What is too much?

15 A. Overdose.

16 MR. EHSAN: Object to the form.

17 BY MR. BILEK:

18 Q. Is that -- you mean death for the
19 woman, overdose at that level? What do you
20 mean "overdose"?

21 MR. EHSAN: Object to the form.

22 THE WITNESS: So you are not

1 providing just maintenance, but you are, you
2 know, inducing all of the side effects and
3 adverse effects of the opioid.

4 BY MR. BILEK:

5 Q. So your position is that during
6 pregnancy, the woman should not reduce their
7 dose?

8 A. I didn't say that.

9 Q. Okay. I mean, generally, do you
10 recommend to try to have a minimum dose of
11 opioids?

12 A. Define "minimum."

13 Q. I'm just asking you, Doctor. Are
14 you looking at each individual case, would you
15 want them to have the minimum dose of the
16 opioid?

17 A. So minimum --

18 MR. EHSAN: Object to the form.

19 THE WITNESS: Minimum can be used in
20 a variety of ways. That's why I was asking.
21 To me, the minimum dose is, as I previously
22 said, enough.

1 BY MR. BILEK:

2 Q. And you have no opinion on what
3 enough is?

4 A. That's highly individualized.

5 MR. EHSAN: Object to the form.

6 BY MR. BILEK:

7 Q. The -- do you think that opioids are
8 appropriate medicine for chronic pain?

9 MR. EHSAN: Object to the form.

10 THE WITNESS: In my practice, I
11 rarely deal with chronic pain and when I do,
12 it's in a small number of infants in a neonatal
13 intensive care unit.

14 BY MR. BILEK:

15 Q. Do you have any opinion as to
16 whether women that are pregnant should be
17 taking opioids for chronic pain?

18 MR. EHSAN: Object to the form.

19 THE WITNESS: That's asking me
20 opinions about the medical management of women
21 during pregnancy and with the exception of the
22 qualifiers I had made above in terms of my

1 expertise, I'm not an obstetrician. It's not
2 an issue that comes up for me.

3 BY MR. BILEK:

4 Q. Why are opioids a controlled
5 substance?

6 MR. EHSAN: Object to the form.

7 BY MR. BILEK:

8 Q. What is your understanding?

9 MR. EHSAN: Same objection.

10 THE WITNESS: Well, I am also
11 trained in history and medical history, and
12 there are many historic reasons for that. You
13 know, why are certain drugs in that category
14 and other drugs not. Sometimes that's because
15 of the nature of the drug, that sometimes
16 that's because of the nature of the way that
17 aspects of society deal with the drug.

18 BY MR. BILEK:

19 Q. Well, do you have any opinion of why
20 opioids are a controlled substance?

21 A. I have an opinion about why it makes
22 sense that they are controlled substances.

1 Q. Okay. What is that?

2 A. Because like certain other classes
3 of drugs, there is the possibility of misuse
4 and abuse.

5 Q. And one of the misuse problems with
6 opioids is addiction, right?

7 MR. EHSAN: Object to the form.

8 THE WITNESS: Well, misuse and
9 addiction are really quite different things.
10 One can be addicted meaning tolerant to an
11 opioid without there being any misuse.

12 BY MR. BILEK:

13 Q. Okay. Are opioids -- do you have
14 any understanding of whether opioids are
15 addictive?

16 A. Yes, I do.

17 Q. What is that opinion?

18 A. Yes, they can be.

19 Q. And one of the reasons why the
20 opioids has increased in this country is
21 because of their addictive nature. Wouldn't
22 you agree?

1 MR. EHSAN: Object to the form.

2 THE WITNESS: I don't think I have a
3 direct opinion about that. My opinion is that
4 for a whole variety of societal and economic
5 and other reasons, that many people
6 self-medicate and opioids are one class of
7 drugs with which one can self-medicate.

8 BY MR. BILEK:

9 Q. And one that potentially is very
10 addictive to some people, correct?

11 A. Like certain other classes of drugs,
12 yes, it can be.

13 Q. And for the issue for women in
14 particular, that the opioids with respect to
15 women are -- can be -- strike that.

16 Do you have any opinion of whether
17 opioids affect women differently than men?

18 A. I'm sorry. You got garbled.

19 Q. Do you have any opinion of whether
20 or not opioids affect women differently than
21 men?

22 MR. EHSAN: Object to the form.

1 THE WITNESS: Whether opioids affect
2 women differently from men? You are not
3 speaking about pregnancy obviously.

4 BY MR. BILEK:

5 Q. Correct.

6 A. Many drugs affect men and women with
7 differences. I'm no expert on the sex
8 differences in metabolism or effects of
9 specific opioids.

10 Q. Does the opioid cross the placenta
11 barrier?

12 MR. EHSAN: Object to the form.

13 THE COURT REPORTER: I'm sorry.
14 Could you repeat that question.

15 THE WITNESS: Do opioids cross --

16 MR. BILEK: Do opioids cross the
17 placenta barrier in a pregnant woman.

18 THE WITNESS: Placenta barrier.

19 THE COURT REPORTER: Oh, okay.

20 MR. EHSAN: Same objection.

21 THE WITNESS: Many do, yes.

22 BY MR. BILEK:

1 Q. Which ones don't?

2 A. Well, there are some synthetic ones
3 that don't, however, their metabolites do. So
4 strictly speaking, your question asks, you
5 know, is the native drug, you know, versus
6 potentially biologically active metabolites.

7 Q. So on the synthetics, you have --
8 what you are saying is the mechanism of
9 crossing the placenta barrier is different; is
10 that correct?

11 MR. EHSAN: Object to the form.

12 THE WITNESS: Different from what?

13 BY MR. BILEK:

14 Q. The actual opioid.

15 MR. EHSAN: Same objection.

16 THE WITNESS: The same transport
17 mechanisms are operative. The specifics of any
18 given drug are going to differ from any other
19 given drug.

20 BY MR. BILEK:

21 Q. But opioids do affect the fetus,
22 correct?

1 A. Correct.

2 Q. And do you know if there is any safe
3 dose for an opioid to a fetus?

4 A. I'm sorry. Again, repeat. Are
5 there any --

6 Q. Is there a safe dose for an opioid
7 to a fetus?

8 MR. EHSAN: Object to the form.

9 THE WITNESS: So I am trying to
10 figure out how to interpret that question.
11 Usually in terms of drugs, when one speaks of
12 safe, one speaks of within a range that does
13 not cause harm, deleterious effects. There are
14 no proven deleterious effects of an opioid per
15 se on fetal development.

16 BY MR. BILEK:

17 Q. You are saying opioids are safe to
18 the fetus?

19 MR. EHSAN: Object to the form.

20 THE WITNESS: That's a different
21 question. The previous question was a safe
22 dose. Now you are asking me about safe

1 generally; is that correct?

2 BY MR. BILEK:

3 Q. I was amazed at your answer,
4 frankly, so I am trying to understand.

5 We know opioids cause NAS, right?

6 MR. EHSAN: Object to the form.

7 THE WITNESS: Opioid use during the
8 latter part of pregnancy is one of the causes
9 of NAS, correct.

10 BY MR. BILEK:

11 Q. And NAS is something that we --
12 people would not want their child to have,
13 correct?

14 MR. EHSAN: Object to the form.

15 THE WITNESS: Yes.

16 BY MR. BILEK:

17 Q. NAS is a harm to the child?

18 MR. EHSAN: Object to the form.

19 THE WITNESS: Not appropriately
20 treated, no.

21 BY MR. BILEK:

22 Q. So you say NAS is not a harm to the

1 child?

2 A. Appropriate treatment of NAS does
3 prevent harm, yes.

4 Q. Okay. Would NAS -- what are the
5 symptoms of a baby that is born with NAS?

6 A. Okay. To answer that, let me first,
7 if I may go back. You asked me a series of
8 questions about the fetus. Then you jumped to
9 NAS.

10 Now, NAS is the N. That's the
11 newborn, neonatal. It's not the fetus. The
12 fetus does not experience the equivalent which
13 would be FAS, fetal abstinence syndrome, unless
14 the mother withdraws herself or a physician
15 inappropriately withdraws her.

16 BY MR. BILEK:

17 Q. But if she doesn't withdraw from the
18 opioids, the potential is that the baby is
19 going to be born with NAS, correct?

20 A. That is a potential. Absolutely.

21 Q. And NAS -- I want you -- you would
22 consider NAS a harm?

1 MR. EHSAN: Object to the form.

2 THE WITNESS: I'm going to ask you
3 to define "harm" just so I know what you mean.

4 BY MR. BILEK:

5 Q. Would you want your baby to be born
6 with NAS, Doctor?

7 A. I would not want my baby to be born
8 with NAS. However, if my wife had a condition
9 for which she required to have opioids
10 prescribed, what I wouldn't want is for her and
11 the fetus to undergo withdrawal. What I very
12 much would want is the safe approach that we
13 deal with the treatment of the NAS once the
14 baby is born.

15 Q. Now, so is it your opinion that
16 babies born with NAS have no long-term health
17 consequences?

18 A. That, of course, is a very important
19 question and one that has been asked and has
20 been studied and is being studied for several
21 decades. It's a very messy area to study.
22 Sorry for a longer response.

1 It's messy because humans are not
2 laboratory animals where all the variables can
3 be controlled. Instead, one needs to deal with
4 all of the different complicating factors.

5 So, yes, there have been studies
6 that show adverse effects in babies who have
7 had NAS; however, it has not been possible to
8 tease out those effects from problems of
9 maternal depression, stress which induce
10 self-medication, family violence, chaotic
11 lifestyle, polydrug use, and a host of other
12 factors.

13 Fortunately, with two other bits of
14 information that are very reassuring on this
15 topic, one is that among those many things I
16 just mentioned in women who are not exposed to
17 NAS, there are follow-ups and we know the
18 potential deleterious effects of those things
19 aside from NAS.

20 And, secondarily, there are some
21 studies in which maternal opioid prescriptions
22 has been the main factor without all of the

1 other socioeconomic, other kinds of factors,
2 and those are very reassuring that per se,
3 there are no known long-term effects of babies
4 who in utero have been exposed to opioids.

5 Q. So your opinion is that -- and we
6 will go through this in quite some detail but I
7 just want to pin you down.

8 Your opinion is, there are no
9 long-term deleterious effects from a child
10 being born with NAS?

11 MR. EHSAN: Object to the form.

12 THE WITNESS: Let me requalify what
13 I answered. What I answered is that the bulk
14 of the studies in the literature on this show
15 that deleterious consequences for babies who
16 had NAS are very difficult to tease out from
17 the context of all of these other factors, but
18 to the extent that they can be, there have been
19 no demonstrated per se opioid exposure
20 consequences.

21 BY MR. BILEK:

22 Q. So are you saying it's uncertain or

1 that -- or are you saying in your opinion it's
2 extremely unlikely. What is your opinion?

3 MR. EHSAN: Object to the form.

4 THE WITNESS: When you asked me
5 about certainty, I personally think nothing in
6 life is certain. I think the sun will come up
7 tomorrow. I think it is very likely that it
8 will, but I can't predict that it will. I have
9 no certainty in that sense.

10 Similarly, in medicine and in
11 science, certainty is elusive. Possibilities,
12 probabilities are what we deal with. From the
13 current medical literature, medical experience,
14 it looks very unlikely.

15 BY MR. BILEK:

16 Q. So your opinion that it's very
17 unlikely. What do you base that opinion upon?

18 A. The sum of the follow-up data where
19 one can start to tease apart opioid exposure
20 from the rest of the context.

21 Q. What scientific studies are you
22 relying on for very uncertain?

1 A. I cited several of them in my
2 report.

3 MR. EHSAN: Objection.

4 BY MR. BILEK:

5 Q. Well, let's go to your report and
6 tell me which ones you are relying on.

7 A. If I may, let me read you some of
8 the operative statements from my report from
9 the top of Page 6.

10 Q. Doctor, Doctor, this deposition will
11 take forever if you're just going to give me
12 stuff -- I want a scientific peer-reviewed
13 study that backs up what you just said.

14 A. Yeah. This -- the length of this
15 deposition will be what it is, not necessarily
16 because I choose to read a statement. Instead,
17 I will give you some of those references.

18 In my report on page -- let me
19 finish, sir. I am giving you what you asked
20 for. I am giving you references, would you
21 like them?

22 Q. I would.

1 A. Thank you.

2 Page 10, as I started to say, of my
3 report, Reference No. 38.

4 Q. Page 10.

5 A. Reference No. 39.

6 Q. 38, 39.

7 A. 40.

8 Q. 40.

9 A. Those are the three references at
10 the time of this report that I cited, and I
11 need to say that these are not meant to be
12 comprehensive. The citation I made were meant
13 to be illustrative. There are other --

14 Q. Doctor.

15 A. You keep cutting me off. You keep
16 cutting me off. I am trying to let you finish.
17 Please let me finish. If I take a breath, it
18 is for the ability of the court reporter --
19 recorder to be able to continue. I'm sorry.

20 I said there are other references
21 perhaps that have come out after the time of
22 the report that are listed in that other

1 document. Thank you. I'm done.

2 Q. What other report, other than these
3 three, are you relying on?

4 A. What is it called? The ML -- three
5 letters, a list of references. I don't have it
6 in front of me. That includes some references
7 that are more up to date than from when I wrote
8 the report.

9 Q. I have no idea what you are talking
10 about.

11 MR. EHSAN: I think, Dr. Rubin, are
12 you referring to material considered list? It
13 is attached to what has been marked as Exhibit
14 2.

15 THE WITNESS: Thank you. I knew the
16 M. I didn't remember the rest.

17 Well, I, you know, there are 72
18 references there, you know, there are probably
19 at least two or three that essentially review
20 the same issues as in the three that I cited
21 for you.

22 BY MR. BILEK:

1 Q. Doctor, at lunch, you can tell me
2 which ones of the 72 that -- after lunch, you
3 can look and try to figure out whether there
4 are anymore.

5 A. Thank you. Does that mean we are
6 breaking for lunch soon?

7 MR. EHSAN: Objection.

8 BY MR. BILEK:

9 Q. It's -- sure. We will be breaking
10 for lunch.

11 A. I will do that.

12 Q. Thank you. Now, are there studies
13 that are on the other side that say there are
14 long-term deleterious effects from NAS?

15 A. Yes. As I tried to clarify before,
16 there are studies that look at deleterious
17 effects that have occurred in babies who
18 received a diagnosis of NAS. However, they
19 have not been able to state that NAS or the
20 opioid exposure was the cause of those
21 deleterious effects.

22 Instead, there are many other

1 aspects of the condition of those babies, the
2 social condition, et cetera, and also for
3 polypharmacy, that are known to be the case.

4 So in sum, there are associations,
5 meaning true and true, but there are no causal
6 relationships. However, when -- thank you.

7 When it's possible to tease out as I
8 previously mentioned, the effects of the
9 opioids per se or a little bit more cleanly,
10 then we can see that there has not been a
11 demonstration of deleterious long-term effects.

12 Q. So your opinion, I mean, is that if
13 a woman is purely -- the NAS is purely caused
14 by opioids, no other drug involved, just
15 opioids, that first of all, if it's just pure
16 opioids, do you have an opinion of whether just
17 having taken opioids during pregnancy, that
18 that alone could cause NAS?

19 MR. EHSAN: Object to the form.

20 THE WITNESS: So that question, as I
21 heard it, sort of slid over a few things. One
22 is that opioids without other drugs, but not

1 stating whether it's opioids without all of the
2 other social and psychological conditions, and
3 the second kind of elision was, you started off
4 by asking me about long-term consequences, but
5 you ended your question about whether opioids
6 can cause NAS.

7 I'm trying to answer, you know, very
8 explicitly, but that question wandered too much
9 for me to know what question you were asking.

10 BY MR. BILEK:

11 Q. If a woman only takes opioids, could
12 she have a child born with NAS?

13 A. Yes.

14 MR. EHSAN: Object to the form.

15 BY MR. BILEK:

16 Q. And if that child is only exposed to
17 opioids and has NAS, are you saying that the
18 science is novel, that that child would have no
19 long-term consequences with NAS?

20 MR. EHSAN: Object to the form.

21 THE WITNESS: To the extent that all
22 of the other messy stuff can be teased apart in

1 free living humans, to the extent that maternal
2 depression, chaotic household, family violence,
3 removal from the household of the child,
4 poverty, et cetera, et cetera, to the extent
5 that those can be sorted out, opioid exposure
6 per se without any of the rest of the stuff has
7 not been demonstrated to have any
8 neurodevelopmental consequences for children.

9 BY MR. BILEK:

10 Q. Is this a subject that needs more
11 study, or is it open and shut that there is no
12 long-term consequences?

13 MR. EHSAN: Object to the form.

14 THE WITNESS: I'm sorry. We are
15 kind of getting back to the same thing as
16 certainty for me. Nothing in the world is
17 certain, and nothing in the world is totally
18 open and shut, because there is no absolute
19 certainty. But we kind of go where the -- in
20 science, one goes where the likely answers are
21 going to be.

22 If we did not have all of these

1 decades of research on this topic, I would say,
2 boy, this is a high priority. However, in the
3 context of, as a scientist and as a clinical
4 researcher, I would love for us to study
5 everything. But we need to prioritize.

6 And I'm not saying that the outcomes
7 of babies with NAS is a low priority by any
8 means. What I am saying is that there has been
9 and there is ongoing, much research in this
10 area, and as I have said, it is fortunately
11 very reassuring.

12 BY MR. BILEK:

13 Q. So in your opinion, there is
14 adequate science research being done right now
15 on the long-term -- possible long-term effects
16 of opioid results -- opioid exposure and
17 resulting in an NAS child?

18 MR. EHSAN: Object to the form.

19 THE WITNESS: Yeah. I am hung up on
20 your word "adequate" because it probably means
21 something different from what it means to me.
22 To me, adequate is that knowledge about any

1 topic can never be absolutely adequate, but
2 again, as I said before, we have possibilities,
3 probabilities, we have unlikely things, likely
4 things. We know enough that it looks unlikely
5 that per se opioid exposure causes long-term
6 problems for children, and we are not dealing
7 in a world where research is going to be turned
8 off or turned on in this area. It has been and
9 it continues to be an area of investigation.

10 BY MR. BILEK:

11 Q. What is your understanding of what
12 the plaintiffs are seeking in this case?

13 MR. EHSAN: Object to the form.

14 THE WITNESS: I actually don't know
15 what the specifics are for that.

16 BY MR. BILEK:

17 Q. I mean, one of the things that the
18 plaintiffs are seeking in this case is that --
19 that NAS children should be medically monitored
20 and assessed.

21 Is that something that you disagree
22 with?

1 A. I'm sorry. Again, it's Zoom. That
2 NAS children should be medically monitored. I
3 didn't hear the next word.

4 Q. And assessed.

5 THE COURT REPORTER: And assessed.

6 THE WITNESS: I'm sorry.

7 THE COURT REPORTER: And assessed.

8 THE WITNESS: Medically monitored
9 and assessed. Well, I would say that is the
10 current state of affairs. That already is
11 happening.

12 BY MR. BILEK:

13 Q. You say that the children are being
14 medically assessed and monitored? That's what
15 you are saying?

16 A. You seem quizzical.

17 MR. EHSAN: Object to the form.

18 THE WITNESS: You seem quizzical.
19 That surprises me. Yes, that is the case in
20 many instances, and here's the reason why. It
21 is maternal and fetal exposure to opioids or
22 the diagnosis of NAS, even aside from that,

1 invokes variably developmental follow-up, child
2 protective services, increased social services,
3 in many, maybe theoretically all parts of the
4 country, so that a baby who has NAS depending
5 on where you are in the country, child services
6 are involved, sometimes the legal aspect of
7 that is involved.

8 Pediatricians are certainly aware of
9 NAS, routine pediatric care is -- aside from
10 vaccinations, is largely a measure of
11 developmental follow-up. So surely, all
12 infants are being medically monitored, and on
13 top of that, because of this very nonrandom
14 association of social deprivation, economic
15 deprivation, you know, potentially legal
16 matters that -- protective services, social
17 services, law enforcement variably are also
18 involved. Yes.

19 BY MR. BILEK:

20 Q. So you are saying -- I mean, let me
21 just make clear for the record.

22 You are saying that all NAS children

1 are currently being monitored for long-term
2 problems?

3 A. Now you are asking a different
4 question.

5 MR. EHSAN: Object to the form.

6 THE WITNESS: First of all, I never
7 said "all" because who knows about all. I said
8 in many, if not most, maybe all parts of the
9 country, these different things happen.

10 The other part is that you didn't
11 ask me before -- you didn't use the words
12 "long-term." Now you are asking about
13 long-term. So tell me what you mean by
14 "long-term."

15 BY MR. BILEK:

16 Q. Well, I think that's an interesting
17 point.

18 You're -- you don't -- you are not
19 involved in the long-term care of children, are
20 you?

21 A. Define "long-term," please.

22 Q. You are a NICU person, and you are

1 not responsible for children -- you don't see
2 children over, like, four months of age?

3 A. No. That's not true at all.

4 Q. What is the oldest child you see
5 right now?

6 A. So neonatologists take care of
7 hospitalized newborns. Some of those newborns
8 are several months of age including more than
9 four months, occasionally, hopefully not too
10 often, they are close to a year of age.
11 Neonatologists also do follow-up which includes
12 developmental follow-up and that typically
13 happens to two to three years of age.

14 On top of that, I will speak about
15 myself, not about neonatology as a profession.
16 I have organized and supervised child
17 development programs in several institutions,
18 including follow-up, up through that period and
19 then transfer over into other developmental
20 pediatricians.

21 I hope that answers the question of
22 whether I see babies who are under four months

1 of age.

2 Q. Well, my question was: What is the
3 oldest child you are treating right now?

4 A. I'm not treating any child right
5 now, and that's not to be facetious. I do
6 several weeks during the year where I am
7 primarily responsible as the attending
8 physician. Aside from night call, I haven't
9 done that for the last three weeks, but I will
10 again within another week from now. Again, I
11 am attempting to be --

12 Q. Well, again --

13 A. -- I am just attempting to be
14 precise. I am not attempting -- I am not
15 attempting -- may I? I am not attempting to
16 lengthen this deposition. I am attempting to
17 clarify vague questions on occasion and I am
18 just trying to answer to the best that I can.

19 Q. I got you. So to the best of your
20 knowledge, what is the oldest child you have
21 treated in the last five years?

22 A. Three years.

1 Q. Three years, five years, whatever.

2 A. I just said three years.

3 Q. Okay. Three years. Three years
4 old. Okay.

5 Now, the issue of long-term
6 assessment of NAS children. How many in your
7 opinion are being properly long-term monitored
8 and assessed?

9 MR. EHSAN: Object to the form.

10 THE WITNESS: NAS children, like all
11 children, as long as there is some consistency
12 of healthcare which unfortunately there is not
13 for everybody in the country, but when you are
14 in healthcare, you have ongoing assessment
15 throughout childhood and adolescence until the
16 time when you transition over to being cared
17 for by adult physicians.

18 BY MR. BILEK:

19 Q. Well, let's go to the population of
20 the NAS children. Are these primarily people
21 that are in vulnerable communities?

22 A. You are garbled again.

1 MR. EHSAN: Object to the form.

2 THE WITNESS: Are these people who
3 are in what sort of communities?

4 BY MR. BILEK:

5 Q. Vulnerable -- economically
6 vulnerable. People lacking healthcare.

7 MR. EHSAN: Object to the form.

8 THE WITNESS: To my best
9 recollection, somewhere in excess of 25 percent
10 of children in our country fit that
11 description. One tries to -- many of us try
12 and do our best to assure that an individual
13 and at a societal level, that healthcare
14 services and social services are available to
15 moms and to children. That's not an NAS issue.

16 BY MR. BILEK:

17 Q. I understand. Now let's talk about
18 NAS children.

19 How many do you think there are
20 disproportionate amount of NAS children in that
21 25 percent that are in the United States
22 globally?

1 MR. EHSAN: Object to the form.

2 THE WITNESS: Because drug abuse and
3 that includes opioids as well as polypharmacy
4 use for self-medication or whatever, because
5 that is more common in vulnerable populations,
6 it certainly is not exclusive to vulnerable
7 populations because it is more common, yes, it
8 will be more common exposure.

9 BY MR. BILEK:

10 Q. Now, the -- another goal of the
11 plaintiff's case is to see a science panel
12 appointed to study possible long-term effects
13 on these NAS children especially in vulnerable
14 areas.

15 Do you understand that?

16 MR. EHSAN: Object to the form.

17 THE WITNESS: You just informed me
18 of that.

19 BY MR. BILEK:

20 Q. Okay. Assume that is true. Is that
21 something that you think is something that
22 would be a meritorious goal?

1 MR. EHSAN: Object to the form.

2 THE WITNESS: You know, to answer
3 that, I think that's -- I'm sorry. I need to
4 turn off my phone. I apologize.

5 I think that is not a meritorious
6 goal as much as that it is a statement of
7 the -- the currency of science in healthcare.
8 The issue of NAS, even more so the issue of
9 vulnerable children, is a high priority for the
10 professional organizations that I belong to as
11 a pediatrician, and many other organizations
12 and many other societal organizations, as well
13 as the study of child development including but
14 beyond NAS is also something that is ongoing.

15 National Institutes of Health, other
16 organizations already are focusing on this.
17 So, yes, I think it's important --

18 BY MR. BILEK:

19 Q. Do you --

20 A. Yes. I think it's important, and
21 yes, I think it is already happening.

22 Q. And do you think that that's -- so

1 you think that that's being adequately studied
2 right now by other organizations?

3 A. Adequately gets us back to the
4 previous discussion of the word "adequately."
5 No need to rehash that probably. When you say
6 "other organizations," other as opposed to
7 whom, just so I understand.

8 Q. Well, you are the one that was
9 saying that these long-term -- possible
10 long-term health effects from an NAS child were
11 being studied.

12 My question was: Is it being done
13 to a sufficient degree in your mind?

14 A. That actually was not your question.

15 MR. EHSAN: Object to the form.

16 THE WITNESS: If you would like us,
17 we could read back your question. I'll respond
18 to both questions.

19 BY MR. BILEK:

20 Q. I would just like you to answer that
21 question, Doctor.

22 A. You want me to answer that question.

1 Could you repeat that question.

2 Q. Do you think that the other
3 organizations are studying NAS long-term
4 effects to an adequate degree in these -- in
5 these areas with vulnerable children?

6 MR. EHSAN: Object to the form.

7 THE WITNESS: So my response to
8 "other organizations," because I use that in a
9 restricted way, to other organizations is that
10 -- for this topic of the scientific study, I
11 mentioned NIH for one, and I said there are
12 many other organizations. What I mean by other
13 organizations is that the academic, medical,
14 psychological, social work, behavioral
15 community already has set this as a priority.

16 There are grants being awarded,
17 there are contracts being awarded. There are
18 people who study this in other ways and the
19 evidence of that is the large number and
20 increasing number of follow-up studies. In
21 that sense, I say this is already a priority
22 and it's already ongoing.

1 When you ask me about -- so that's
2 the others. When you ask me about the word
3 "adequate," theoretically, nothing is adequate
4 because nothing is ever certain. I go back to
5 what we know now, strongly implies that there
6 is very little, if any long-term effect by
7 opioid exposure per se, emphasize "per se," on
8 later development.

9 BY MR. BILEK:

10 Q. So just to be clear, do you -- in
11 your expert opinion, there is sufficient
12 scientific studies going on right now?

13 MR. EHSAN: Object to the form.

14 THE WITNESS: Sufficient, there is a
15 lot of study going on right now.

16 BY MR. BILEK:

17 Q. Is it -- is it -- would you like to
18 see more?

19 MR. EHSAN: Object to the form.

20 THE WITNESS: We can discuss the
21 principle of whether there are absolutes or
22 not. Again, I always would like to see more,

1 but I realize that --

2 BY MR. BILEK:

3 Q. So --

4 A. No. You've got to let me finish.

5 But I realize that, as I have said enumerable
6 times, we have so much evidence that shows what
7 is and isn't a cause of a later problem.

8 Q. Now, you -- have you ever diagnosed
9 a NAS child and listed a possible cause of the
10 NAS diagnosis as opioid?

11 A. Yes.

12 Q. When have you done that?

13 A. Frequently.

14 Q. Okay. And what -- how do you make
15 that diagnosis?

16 A. So there are definitions of all
17 diagnoses. A definition that is very commonly
18 accepted currently in medicine is the
19 definition that appears in what are called the
20 ICD currently 10 codes, the criteria for making
21 a diagnosis. And because I practice according
22 to the standards of my profession, I adhere to

1 those definitions.

2 I have lost track of the specific
3 question. I'm sorry.

4 Q. I said: How do you make a diagnosis
5 of NAS resulting -- that is caused in part by
6 opioids?

7 MR. EHSAN: Object to the form.

8 THE WITNESS: So that's actually
9 straightforward. Thank you for a
10 straightforward question.

11 I make the diagnosis in that
12 instance by having a baby who exhibits sign
13 symptoms consistent with the profile, the
14 behavioral repertoire of neonatal abstinence
15 syndrome, and I draw the link to the
16 possibility that maternal opioids are involved
17 by having one or both of the following: A
18 documented or suggestive maternal history. The
19 second is a toxicology screening either on the
20 mother or the newborn or both.

21 BY MR. BILEK:

22 Q. And on the maternal history, is one

1 of the things you look at is whether she had an
2 opioid --

3 A. You are garbled again. Whether or
4 not she had an opioid --

5 Q. Whether or not she had an opioid
6 prescription during pregnancy?

7 MR. EHSAN: Object to the form.

8 THE WITNESS: Well, I certainly hope
9 that the only women who have opioid exposure
10 during pregnancy are those who have it
11 prescribed. So certainly, that's part of the
12 history.

13 BY MR. BILEK:

14 Q. And that would be one of the reasons
15 that -- and in making your diagnosis, that the
16 NAS is caused in part by opioids?

17 MR. EHSAN: Object to the form.

18 THE WITNESS: So, yes, in the
19 following sense: Neonatal abstinence syndrome
20 is defined as a -- again, the spectrum profile,
21 repertoire of behaviors and other symptoms in
22 the newborn. When there is not a different

1 attributable reason from the fact that there is
2 documentation of the baby when a fetus being
3 exposed to opioids or other drugs that can
4 induce this clinical spectrum.

5 BY MR. BILEK:

6 Q. And when opioids are prescribed, my
7 point is, that could be one of the causes of
8 the NAS?

9 MR. EHSAN: Object to the form.

10 THE WITNESS: Certainly. NAS is
11 neonatal abstinence. The abstinence has to
12 come from being abstinence of something.

13 BY MR. BILEK:

14 Q. Right. Now in your diagnosing, do
15 you use the Finnegan test?

16 MR. EHSAN: Object to the form.

17 THE WITNESS: I do, because it is by
18 far the most common screening form that is
19 utilized and has been utilized for several
20 decades in the United States.

21 BY MR. BILEK:

22 Q. And it is widely used throughout by

1 neonatologists?

2 MR. EHSAN: Object to the form.

3 THE WITNESS: Yes, that's what I
4 just said.

5 BY MR. BILEK:

6 Q. Okay. And the neonatologists rely
7 on this test in making an NAS diagnosis?

8 A. Not directly, no.

9 Q. In what sense is it not direct?

10 A. So the specific use of the Finnegan
11 or modified Finnegan score -- it has gone
12 through a few reiterations since Laura Finnegan
13 and her colleagues published this in the
14 mid-1970s.

15 And by the way, it wasn't meant for
16 clinical use, it was meant for research use,
17 but, being there, it understandably is used for
18 clinical use. But its specific use is for
19 initiating and monitoring therapy for NAS.

20 Q. Well, I mean, you would agree that
21 it is part of the diagnostic tool of -- for a
22 medical provider to diagnose NAS?

1 A. Yes.

2 MR. EHSAN: Object to the form.

3 BY MR. BILEK:

4 Q. I want to turn to fentanyl.

5 MR. EHSAN: Tom, if you are going
6 to change subjects, I know that it's still
7 early morning for us, but it's 1 p.m. Eastern
8 Time.

9 MR. BILEK: I'm sorry. You are so
10 right. Let's go take a lunch break. I am
11 forgetting -- for me, I am just starting to
12 wake up.

13 THE WITNESS: Oh, great. Oh, I'm
14 glad. I'm glad to hear that. I do have one
15 question in all seriousness, because I'll need
16 to move my car. I brought lunch, but I did not
17 bring dinner. Do you get the drift of my
18 question?

19 MR. BILEK: Well, I'm going to try
20 to go, but one thing that would be very helpful
21 for me is for you to be answering the question
22 asked, but we will get into an argument again

1 on that --

2 THE WITNESS: We won't get into an
3 argument about that. The clearer the question,
4 the easier the answer. We'll both try our
5 best.

6 MR. BILEK: Okay.

7 THE WITNESS: See you after lunch.

8 MR. BILEK: We will see you guys in
9 one hour. Thank you.

10 (A short recess was taken.)

11 MR. EHSAN: Tom, I apologize, Tom.
12 Before we get going, somebody made a good point
13 during the lunch break. Can we have an
14 agreement that an objection by me is an
15 objection for all defendants so we don't have
16 other people potentially objecting to things.

17 MR. BILEK: Well, we can deal with
18 that for the future.

19 MR. EHSAN: Okay.

20 MR. BILEK: Now, back on the record.

21 BY MR. BILEK:

22 Q. Doctor, I want to talk about

1 fentanyl for a little bit.

2 Are you familiar with fentanyl?

3 A. Yes.

4 Q. Fentanyl is what you would refer to
5 as a designer opioid?

6 MR. EHSAN: Object to the form.

7 THE WITNESS: No, I don't use -- no,
8 I don't use that term.

9 BY MR. BILEK:

10 Q. I'm sorry. I am trying to remember
11 what you called -- you called them synthetic.
12 Is that the term you used?

13 A. That's correct.

14 Q. And generally, what is a synthetic
15 opioid?

16 A. It's an opioid that the chemical
17 structure of which does not occur in nature but
18 is synthesized.

19 Q. And is fentanyl more or less
20 addictive than a naturally occurring opioid?

21 MR. EHSAN: Object to the form.

22 THE WITNESS: I don't know the

1 answer to that. Fentanyl on a mass basis is
2 more potent.

3 BY MR. BILEK:

4 Q. Certainly, you would agree that it
5 is a stronger opioid than the normal, natural
6 opioid?

7 MR. EHSAN: Object to the form.

8 THE WITNESS: A normal opioid
9 doesn't have any particular meaning. It's
10 stronger than morphine and often things are put
11 into morphine equivalence.

12 BY MR. BILEK:

13 Q. Stronger than morphine, how about
14 heroin?

15 THE COURT REPORTER: I'm sorry.
16 Could you repeat that?

17 BY MR. BILEK:

18 Q. Heroin, how does it compare to
19 heroin?

20 MR. EHSAN: Object to the form.

21 THE WITNESS: How does fentanyl
22 compare to heroin?

1 BY MR. BILEK:

2 Q. Yes, sir.

3 A. I don't know the exact answer. I
4 think that depends upon the purity of the
5 heroin.

6 Q. Do you know who manufactures
7 fentanyl?

8 A. No, I don't.

9 Q. I will tell you it's -- Teva
10 manufactures fentanyl.

11 And do you live in Virginia or
12 Maryland or Washington, D.C.? Where do you
13 live?

14 MR. EHSAN: Object to the form.

15 THE WITNESS: Multiple choice. I
16 live in Washington, D.C.

17 BY MR. BILEK:

18 Q. Washington, D.C. Okay.

19 Well, are you aware of the State of
20 Virginia filing suit against, A, the opioid
21 manufacturers?

22 A. Not specifically, no.

1 Q. Do you know generally that many of
2 the states have filed suits against the opioid
3 manufacturers?

4 MR. EHSAN: Object to the form.

5 THE WITNESS: I know at least
6 several states have.

7 MR. BILEK: Could the court reporter
8 give Exhibit 5 to the witness, please.

9 (Deposition Exhibit 5 was marked for
10 identification.)

11 THE COURT REPORTER: The witness has
12 Exhibit 5.

13 BY MR. BILEK:

14 Q. Exhibit 5 is a press release
15 compiled by the Office of the Attorney General
16 for the Commonwealth of Virginia that was
17 issued on October 31, 2019.

18 And in it, I just want you to --
19 we're going to go through some of these things
20 that were going on with fentanyl.

21 And in this case, Teva
22 Pharmaceuticals is being sued, and what is

1 being alleged is that there was an unlawful,
2 complex decades-long campaign to boost sales of
3 fentanyl. The most --

4 A. I'm sorry. I'm sorry. I'm sorry to
5 interrupt you, but it looks like you are
6 reading. What are you reading from? Anything
7 in this document?

8 Q. I am reading from Exhibit 5. We are
9 going -- we are going to assume some facts --

10 A. Well, I'm not assuming anything
11 until you tell me what it is that you are
12 reading and where you are reading because I
13 have not seen this document before.

14 Q. Okay. Exhibit 5, first -- first
15 full paragraph.

16 A. I'm sorry. What page? Zoom is bad.

17 Q. First page.

18 A. First page.

19 Q. Okay. And it talks about:

20 "Attorney General Mark Herring today filed suit
21 against opioid manufacturer Teva
22 Pharmaceuticals, USA, Inc., and its

1 predecessor, Cephalon, Inc., for engaging in
2 what he alleges is an unlawful, complex,
3 decades-long campaign to boost sales of
4 fentanyl."

5 Do you see that?

6 A. I'm reading it with you.

7 Q. "The most potent narcotic currently
8 approved for human use by marketing its
9 rapid-acting fentanyl drugs for unapproved and
10 unsafe uses, and by knowingly and intentionally
11 downplaying the risk of its drugs while
12 overselling the benefits."

13 Do you see that?

14 A. I do.

15 MR. EHSAN: Object to the form.

16 BY MR. BILEK:

17 Q. Now, first of all, do you have any
18 opinion on whether -- or have made any
19 investigation on whether Teva engaged in any
20 illegal marketing scheme?

21 A. I don't know any of the details
22 besides what you are reading to me, but I think

1 it's important for me to add that fentanyl is
2 not prescribed during pregnancy, you know, for
3 the purposes we have talked about.

4 I use fentanyl sometimes frequently
5 in the newborn ICU, never for treatment of
6 neonatal abstinence syndrome and the whole
7 issue of fentanyl or this is totally aside from
8 my expertise and my report.

9 This deposition is supposed to be
10 about my report and the questions that I have
11 been asked. You are perfectly entitled to ask
12 me any question you would like but this has no
13 relevance to neonatal abstinence syndrome.

14 Q. You are saying fentanyl won't cause
15 neonatal abstinence syndrome?

16 A. I did not say anything close to that
17 and you know it.

18 MR. EHSAN: Object to the form.

19 THE WITNESS: I said that it is not
20 prescribed for women during pregnancy unless
21 they are in the hospital for some other reason.

22 And I said, if I have to repeat

1 everything that I have said twice so that you
2 fully understand or hear what my responses are,
3 it will take us through dinner, sir. I also
4 said that I used fentanyl but never for
5 neonatal abstinence syndrome.

6 BY MR. BILEK:

7 Q. I am getting to this, Doctor,
8 because right now, this issue of saying that
9 fentanyl is not prescribed to women during
10 pregnancy, it simply is a fact not in evidence.
11 In fact, it's going to be contrary to what the
12 attorney general here is filing suit on.

13 A. I did not say that. If you continue
14 to try and put words that I did not say in my
15 mouth, this will take forever, because I will
16 ask to have every one of my statements repeated
17 back so that you can hear them more clearly.

18 I said fentanyl is not prescribed
19 for women unless they are hospitalized for some
20 other reason. Listen to me, and we will get
21 done with this so much earlier, sir.

22 Q. Sir, you are just -- your statement

1 assuming that fentanyl is not being prescribed
2 to women that are of child-bearing age outside
3 of the hospital.

4 Is that what your assumption is?

5 MR. EHSAN: Object to the form.

6 THE WITNESS: I have stated clearly
7 what the uses for fentanyl are and aren't. I
8 maintain that.

9 BY MR. BILEK:

10 Q. And do you know whether Teva allowed
11 that off-label uses that it was being used
12 outside of the hospital?

13 A. I have absolutely no idea.

14 MS. O'DONNELL: Object to the form.

15 BY MR. BILEK:

16 Q. And do you have any opinion as to
17 whether fentanyl can cause NAS?

18 A. Virtually any opioid to which the
19 fetus is exposed, depending on the duration and
20 the concentration, can cause NAS. Let me be
21 clear. All babies who have NAS have not been
22 exposed to opioids. All women who take opioids

1 do not have babies with NAS. Clear?

2 BY MR. BILEK:

3 Q. Sir, if you just answer my question.
4 Clear?

5 A. Clear.

6 Q. The issue is fentanyl -- could
7 fentanyl cause a baby to be born with NAS?

8 A. I just answered that.

9 Q. So the answer is yes?

10 A. The answer is yes.

11 MR. EHSAN: Object to the form.

12 BY MR. BILEK:

13 Q. Okay. Now, the issue of whether
14 fentanyl is being prescribed by doctors to
15 women outside of the hospital. I'm going to --
16 I'm going to ask you to assume that it's a
17 fact. Okay?

18 A. That's a hypothetical because it's
19 against commonly-accepted practice.

20 Q. Well, the evidence shows that your
21 understanding of the commonly-accepted practice
22 is wrong. Okay?

1 A. I think that is -- sir, I think
2 that's a highly debatable point. I do not want
3 to argue with you. When you tell me a
4 statement of mine is wrong, at least show me
5 evidence that says it's wrong.

6 In any case, it is -- I do not take
7 care of women during pregnancy, aside from the
8 issues -- you are asking me about stuff that is
9 again, quote, outside of my wheelhouse.

10 BY MR. BILEK:

11 Q. Well, this is my issue because I
12 think it's going to get to your wheelhouse, if
13 you just bear with me.

14 A. I have been bearing with you since
15 9:30 this morning Eastern Time. Let's
16 continue.

17 Q. So this issue of the fentanyl being
18 prescribed to women, assume that's true.
19 Assume to me that the drug manufacturers knew
20 this and targeted vulnerable populations, and
21 when -- I am talking about economically
22 vulnerable populations that we have been

1 discussing. Let's step back.

2 You have written on a -- on socially
3 disadvantaged populations and the unique
4 obstacles that they confront, correct?

5 A. Yes.

6 MR. EHSAN: Object to the form.

7 BY MR. BILEK:

8 Q. And that you -- that's one of your
9 things that you are known for, is talking about
10 social inequality and the fact that these
11 people have obstacles and need help, right?

12 A. I am known for a lot of things.

13 MR. EHSAN: Object to the form.

14 THE WITNESS: I don't know how well
15 I'm known for that or not.

16 BY MR. BILEK:

17 Q. Well, it's something --
18 that's something that is an important issue to
19 you. Would you agree?

20 A. Yes.

21 Q. And the -- the disadvantaged
22 population economically and that have various

1 social issues, those people are at least able
2 to overcome obstacles compared to the average
3 person in the United States.

4 Would you agree with that?

5 A. No. I think you're making a --

6 MR. EHSAN: Object to the form.

7 MS. O'DONNELL: Object to the form.

8 THE WITNESS: I'm sorry. No --

9 THE COURT REPORTER: I'm sorry. Who
10 else objected?

11 MS. O'DONNELL: Lauren O'Donnell for
12 Teva.

13 THE COURT REPORTER: All right.
14 Great. Thank you, Lauren.

15 THE WITNESS: No. I think you're
16 making --

17 MS. O'DONNELL: I also had that
18 prior objection.

19 THE WITNESS: Sorry. Anybody else
20 object?

21 No is my answer. You are making
22 some extreme assumptions, specifically the

1 assumptions that somebody, because of social
2 deprivation, is not capable of choice. That's
3 the implication, is not capable of resilience.

4 I'm not disputing that people have
5 challenges, but I would never characterize a
6 group of people the way that that question
7 implies.

8 BY MR. BILEK:

9 Q. I am not saying, Doctor, that the
10 issue is they can't overcome. I am saying that
11 because of their social circumstances, it is
12 more difficult for them to overcome an obstacle
13 than say yourself that has -- living in
14 Washington, D.C., with the best healthcare in
15 the world.

16 A. There are many --

17 MR. EHSAN: Object to the form.

18 THE WITNESS: There are many
19 disadvantaged people who live in Washington,
20 D.C., in eyesight of the best healthcare in the
21 world.

22 BY MR. BILEK:

1 Q. And, again, these people do not --
2 they have, and I think you -- we talked to
3 them. They have certain challenges that are
4 unique to being in poverty.

5 A. Yes. Poverty presents, obviously,
6 all sorts of life challenges.

7 Q. And so for a drug manufacturer to
8 target people in certain economic
9 circumstances, in poverty, that would be
10 something in your mind that would be
11 exceptionally egregious, right?

12 MR. EHSAN: Object to the form.

13 THE WITNESS: A, and there is only
14 an A and B. A, that is a hypothetical. B,
15 that's totally out of my area of expertise or
16 knowledge.

17 BY MR. BILEK:

18 Q. Well, I am asking you to assume that
19 that occurred. Wouldn't you find that to be
20 exceptionally egregious behavior?

21 MR. EHSAN: Object to the form.

22 THE WITNESS: Pharmaceutical

1 companies like other organizations should
2 adhere to high standards.

3 BY MR. BILEK:

4 Q. Right. And that high standard
5 should be also not targeting socially
6 disadvantaged people with illegal marketing
7 schemes, correct?

8 A. You're stating that --

9 MR. EHSAN: Object to the form of
10 the question.

11 THE WITNESS: You are stating that
12 as a fact or another one of your many
13 hypotheticals?

14 BY MR. BILEK:

15 Q. I am stating that it's a
16 hypothetical that they should not do that. Is
17 that what you believe?

18 MR. EHSAN: Same objection.

19 THE WITNESS: Yeah. Obviously, I
20 don't think people should be targeted for any
21 reason.

22 BY MR. BILEK:

1 Q. Now, the -- going to -- well, let's
2 turn to Exhibit 24, which is -- you will
3 recognize this document.

4 (Deposition Exhibit 24 was marked
5 for identification.)

6 THE WITNESS: First, I have to see
7 it.

8 BY MR. BILEK:

9 Q. Can you identify this document for
10 the record, please.

11 A. This is, if my memory serves me,
12 this is what I referred to on my CV as Page 20,
13 Reference No. 20. It's an article, one of a
14 series of articles in a study where I
15 co-authored with others in studies of preterm
16 babies in neonatal intensive care units in --
17 in New England.

18 Q. And one of the things -- I mean,
19 this is something that you were -- obviously,
20 you wrote, you were deeply involved in this
21 work, correct?

22 MR. EHSAN: Object to the form.

1 THE WITNESS: Yes. That should seem
2 obvious.

3 BY MR. BILEK:

4 Q. Okay. Let's turn to the second
5 page, first full paragraph underneath the box.
6 It says -- well, actually, the last paragraph
7 -- let's see here.

8 Actually, why don't I just have you
9 read what you -- what you wrote, the last
10 sentence of the first paragraph.

11 A. "Reports of long-term adverse
12 behavioral effects in children of
13 narcotic-addicted mothers and in animal studies
14 are disturbing."

15 Q. Is that -- do you take that as a
16 true statement?

17 MR. EHSAN: Object to the form.

18 THE WITNESS: In September of 1998,
19 when this paper was published, that is a
20 reasonable statement. In -- what month are we
21 in? In September of the year 2020, that
22 statement would need to be amended.

1 BY MR. BILEK:

2 Q. Now, we're going to talk about that.

3 So you are saying you don't
4 believe -- you don't believe your own words any
5 more in 1998, correct, you changed your mind?

6 MR. EHSAN: Object to the form.

7 THE WITNESS: Yeah. A more accurate
8 way of putting that is any scientific statement
9 needs to reflect the evidence at that given
10 time.

11 BY MR. BILEK:

12 Q. And you have decided that the
13 science since writing this article in 1998
14 reflects that there are now no long-term
15 effects from -- as a result of being -- having
16 opioid exposure and being born with NAS?

17 MR. EHSAN: Object to the form.

18 THE WITNESS: More evidence, better
19 evidence. We all, even you, change our
20 opinions.

21 I am looking right now at the four
22 references upon which that statement is

1 supposedly based. The first of those is a
2 review article, not data. The second of those
3 is a study in rats. The third of those is a
4 review article about teratogens and
5 teratogenesis. That means birth defects and
6 the study of birth defects.

7 And I can tell you that in the
8 mid-to-later 1990s, that was still an open
9 question. It's been shut. That opioids have
10 not been shown to induce birth defects in
11 children, and I will finish up with the last of
12 the four references which is again a review
13 article that says Methadone and heroin during
14 pregnancy or review of behavioral effects in
15 human and animal offspring.

16 Some of those are animal data which
17 have turned out not to relate to the human
18 brain and that again is a review article.

19 So --

20 BY MR. BILEK:

21 Q. Doctor --

22 A. You are not letting me finish again.

1 So if I can go back and read that
2 sentence again: "Reports of long-term
3 behavioral aspects in children of
4 narcotic-addicted mothers and in animal studies
5 are disturbing." Yes. Those reports are
6 disturbing.

7 The bulk of the literature didn't
8 say that there were effects. It was disturbing
9 not to know and very specifically, it says "in
10 children of narcotic-addicted mothers."
11 Narcotic-addicted mothers being circa 1998.

12 We are talking about a time before
13 many of these synthetic opioids were ever
14 manufactured, much less marketed. We are
15 talking about an era where it was heroin or
16 people who were on maintenance with Methadone.
17 Just to clarify what that says and what it
18 doesn't say.

19 Q. Doctor, I understand. What you are
20 saying is that you no longer agree with that
21 statement, correct?

22 MR. EHSAN: Object to the form.

1 THE WITNESS: I agree with -- right.
2 I agree with the statement that at the point
3 these suspicions were disturbing, and now I am
4 reassured about the effect -- and I can't
5 emphasis this too much, but I will try.

6 That the effects of opioid exposure
7 of the fetus per se -- per se is not known to
8 have deleterious long-term effects.

9 BY MR. BILEK:

10 Q. Okay. Now, is it your opinion since
11 1998, that -- 1998, there has been more studies
12 that showed that there are long-term
13 deleterious effects of opioids -- of opioids
14 causing NAS -- strike that.

15 Would you agree or disagree or have
16 any opinion of whether the rate of evidence
17 since 1998 or whether or not there is more
18 studies or less studies that show that there
19 are long-term deleterious effects from NAS?

20 MR. EHSAN: Object to the form.

21 THE WITNESS: Okay, yes and no. And
22 this is ground that we have gone through in the

1 following way. I have explained what the bulk
2 of literature is, and I have to recharacterize
3 it.

4 I have said that there are many
5 studies that show that some babies with NAS
6 have deleterious outcomes. I have also said
7 that those studies have been often admitted by
8 the very authors have -- the authors have
9 stated that they cannot tease apart the effect
10 of the opioid or the NAS from that broader
11 context, all the social stuff, the
12 polypharmacy, the other drugs, et cetera, et
13 cetera.

14 I have finally said that there are
15 some studies that are able to do that a bit
16 more cleanly, and so yet another time, the bulk
17 or the gist of the scientific literature, as we
18 sit here in 2020, is that there is no defined
19 association of opioid use by the mother,
20 meaning, you know, if mom has been prescribed
21 that, no causal relationship with any in
22 humans, any long-term neurodevelopmental

1 consequences.

2 That is what I have said several
3 times and that's what I'll continue to say
4 because that is an accurate assessment of the
5 medical literature.

6 BY MR. BILEK:

7 Q. You made up your mind. I got that.

8 A. I have made up my mind -- I have
9 made up my mind based on evidence as in the
10 case from 1998 to 2020, as evidence comes in,
11 my opinions which are evidence-based will need
12 to change.

13 Q. Well, I am glad you have got an open
14 mind because we're going to test that. But
15 first, let's go to -- do you know how many
16 hours you have spent, what you billed in this
17 case, for literature review?

18 A. Not offhand, no.

19 Q. Let me tell you, four hours. Do you
20 think four hours is a sufficient time for you
21 to have reviewed and figured out what all the
22 studies are?

1 A. That's not a true statement.

2 MR. EHSAN: Object to the form.

3 THE WITNESS: I have spent many more
4 than four hours on literature review. If you
5 are looking at the billing that I submitted,
6 some of it may say literature review, some of
7 it may say research. Those are close to
8 identical. I have spent a lot more than four
9 hours.

10 BY MR. BILEK:

11 Q. Okay. Well, that's not what your
12 billing records say, but let's go on to --
13 instead of arguing about that.

14 A. There is no argument. There is no
15 argument. What I have done is I've corrected
16 your incorrect statement that I spent four
17 hours and nothing more on literature review.
18 Presented with new evidence that I have just
19 given you, I hope you, too, will change your
20 mind.

21 Q. Okay. We will see.

22 A. We will.

1 Q. My next question I have is: What
2 kind of evidence on long-term study would cause
3 you to be troubled that there are long-term
4 effects stemming from NAS?

5 MR. EHSAN: Object to the form.

6 THE WITNESS: Long-term consequences
7 from NAS. That's a different question from
8 long-term consequences from opioid exposure.

9 BY MR. BILEK:

10 Q. Opioid exposure, NAS. From NAS,
11 long-term consequences for the child being born
12 with NAS due to opioid exposure?

13 A. Two different questions.

14 MR. EHSAN: Object to the form.

15 THE WITNESS: Two different
16 questions deserves two answers. The
17 consequences of NAS themselves should not be
18 deleterious in the following specific sense:
19 Pain, distress, physiologic distress, these can
20 have long-term neurodevelopmental outcomes. A
21 well-written literature including by Dr. Anand
22 who you quoted earlier, one wants to avoid

1 that, when that distress is due to exposure
2 that the fetus had to opioids, one treats the
3 baby with opioids, standard treatment.
4 Well-treated babies with NAS don't have to go
5 through anything that seems like withdrawal.

6 So that's my answer about NAS. NAS
7 that is treated well and basically that means
8 NAS that is treated in the ways that are
9 currently accepted, there shouldn't be
10 long-term effects. Effects of opioid exposure
11 per se in terms of long-term outcomes, I have
12 stated probably a dozen times since this
13 morning. We can read back any one of those
14 answers because they are all the same.

15 BY MR. BILEK:

16 Q. I am asking you a different
17 question. I am asking you: What scientific
18 evidence, what would a properly modeled study
19 that shows -- that would change your mind that
20 babies born with NAS whose mothers were
21 addicted to opioids had long-term problems?

22 A. Okay. The question is a study.

1 MR. EHSAN: Object to the form.

2 THE WITNESS: A study of those
3 babies who have NAS but have that because they
4 were exposed to opioids in utero, correct?
5 Like I have alluded to earlier, a clean study
6 in the sense of a study that is able to account
7 for the other variables that clearly have their
8 own separate impact on long-term -- short or
9 long-term neurodevelopment. Hard thing to do
10 unless you put pregnant women and their
11 newborns into a lab.

12 BY MR. BILEK:

13 Q. So, but one of the things that you
14 could do is compare kids that -- on what their
15 developmental rates are that were born with NAS
16 compared to similarly-situated non-children who
17 were born without NAS.

18 MR. EHSAN: Object to the form.

19 THE WITNESS: What means "similarly
20 situated"?

21 BY MR. BILEK:

22 Q. Same economic circumstances, same

1 social environment.

2 A. You're asking basically a two-prong
3 question. You're asking about a study that
4 would look at babies who have NAS but have NAS
5 because their -- they were exposed as fetuses
6 to opioids and comparing that group to a
7 similar group in other ways that has not had
8 the exposure and not had NAS.

9 I have cited in my report several of
10 those articles that have tried to get out that,
11 and I repeat although it's probably a
12 perseveration at this point, to the extent that
13 that is possible to tease out, there is no
14 defined long-term effect of opioids per se, not
15 all the rest of the stuff, and to do a study
16 such as you propose is intriguing and can't be
17 done on planet earth.

18 Q. What you are saying is, there is no
19 evidence that would ever make you think that
20 there was a -- there are -- that the long-term
21 adverse behavioral effects in children of
22 narcotic-addicted mothers would be disturbing

1 to you?

2 A. Okay.

3 MR. EHSAN: Object to the form.

4 THE WITNESS: Yeah. You are not
5 upsetting me, sir, but you are perplexing me
6 because you keep on saying "so you mean,
7 Dr. Rubin, that" and you give a sentence that
8 not only isn't close, it's in another solar
9 system compared to what I did say.

10 I never said anything like that. I
11 have said the way my opinions are based on data
12 and how those things change. We have gone
13 through that a bunch of times. If you want to
14 keep trying to make me accept that something I
15 didn't say is something you are saying I did
16 say, ain't going to happen.

17 BY MR. BILEK:

18 Q. Well, we will just see what's going
19 to happen.

20 A. We will.

21 Q. The issue of -- in this report, the
22 -- if you turn to the last page.

1 A. I'm sorry. Stop, sorry. What
2 exhibit are you looking at now?

3 Q. I am still looking at Exhibit 24.

4 A. 44?

5 THE COURT REPORTER: 24.

6 THE WITNESS: 24.

7 BY MR. BILEK:

8 Q. 24.

9 A. Tell me where again on Exhibit 24.

10 Q. Go to the last page. The people
11 that you cite to and rely on.

12 A. Okay. I'm on the last page.

13 Q. Who wrote the -- who did you rely on
14 in your first two footnotes?

15 A. Dr. KS Anand.

16 Q. Footnote No. 1: "Relationships
17 between stress responses" -- who wrote that
18 article?

19 A. I just answered you, KS Anand.

20 Q. Right. So Anand -- Dr. Anand, you
21 in the past, in your peer-reviewed literature,
22 relied upon him, correct?

1 A. Yes. For specific things which is
2 what I have said the last few times. You
3 brought Sunny Anand's name up. Let's look at
4 the two references that you're bringing up.

5 The first of these two is called:
6 "Relationships Between Stress Responses and
7 Clinical Outcome in" Newborn -- "Newborns,
8 Infants, and Children." That is a discussion
9 about an area of his expertise which I
10 previously mentioned, which is the importance
11 of stress and stress responses not being
12 treated, not being dealt with, and those -- and
13 the importance of that for long-term
14 deleterious consequences.

15 The gist of that article, frankly,
16 is the reasons to use opioids not -- not to use
17 opioids. Let me go to the second one of those,
18 Anand and a co-author who I don't know.

19 "Neonatal and Pediatric Stress Responses to
20 Anesthesia and Operation." Again, looking at
21 the stresses and the consequences of the
22 stresses that come when, during anesthesia and

1 during surgery, infants are not appropriately
2 medicated. Yeah. That's an area that Dr.
3 Anand is expert in. That's an area that we
4 relied upon him in.

5 Q. Dr. Rubin, have you looked at Dr.
6 Anand's resume?

7 A. I don't recall if -- when I was sent
8 his report, if a -- if his current recent CV
9 was in there or not.

10 Q. Do you know whether -- how many
11 articles he's published on NAS?

12 MR. EHSAN: Object to the form.

13 THE WITNESS: On neonatal abstinence
14 syndrome as the main topic of the article, is
15 that what you are asking me?

16 BY MR. BILEK:

17 Q. Yes, sir.

18 A. No, I don't.

19 Q. Let's try to go through some of
20 these studies and see what you agree with and
21 what you don't.

22 Let's go -- I guess we should go to

1 ones you have reviewed first, and then we'll go
2 through the ones that are probably -- are new
3 to you.

4 Let's start with -- let's go to
5 Deposition Exhibit 15.

6 MR. BILEK: If the court reporter
7 could hand Deposition Exhibit 15 to the
8 witness, please.

9 MR. EHSAN: I object and move to
10 strike the commentary before the question.

11 (Deposition Exhibit 15 was marked
12 for identification.)

13 BY MR. BILEK:

14 Q. Can you identify Exhibit 15?

15 A. It is an article published in the
16 Journal of Health Affairs in February of this
17 year entitled: "Five Year Outcomes Among
18 Medicaid-Enrolled Children With In Utero Opioid
19 Exposure."

20 Q. Okay. One of the -- this is
21 something you've reviewed, right?

22 A. You know, I've reviewed so many

1 articles. The title seems familiar, but I
2 cannot say here for sure whether I have
3 previously reviewed this or not. If it appears
4 in the list, I certainly have reviewed it.

5 Q. Okay. The abstract, if you go to
6 the abstract, it says in about the middle of
7 the paragraph: "Children with in utero opioid
8 exposure."

9 Do you see that?

10 A. Yes.

11 Q. "Children with in utero opioid
12 exposure have a lower predicted probability of
13 recommended well-child visit use at age 15
14 months compared to those with tobacco exposure
15 and those with neither exposure. Children with
16 in utero opioid exposure had a predicted
17 probability of being diagnosed with a pediatric
18 complex chronic condition similar to that among
19 children."

20 Do you see that?

21 A. Of course I do.

22 MR. EHSAN: Object to the form.

1 BY MR. BILEK:

2 Q. Do you see that? Am I reading that
3 correctly?

4 A. I just said yes, I saw it. Yes.
5 You read it correctly.

6 Q. Thank you. So this was looking at
7 trying to give you comparisons still.

8 Now, the -- their conclusions on the
9 last page. I want you to go to that.

10 A. I already have.

11 Q. Okay. It says: "Children diagnosed
12 with NAS have higher probability being
13 diagnosed with a pediatric complex chronic
14 condition."

15 Do you see that?

16 A. Yes.

17 Q. You agree with -- is that something
18 that would trouble you, the finding of this
19 study?

20 A. I am reading that --

21 MR. EHSAN: I object to the form,
22 and I also object to move to strike the

1 prologue before the question was asked.

2 Sorry. Go ahead.

3 BY MR. BILEK:

4 Q. Is this conclusion --

5 A. No. I heard you. I need to answer
6 that by reading it in context so the context is
7 -- allow me to read the next sentence for the
8 record: "Although we did not detect a large
9 magnitude of association between in utero
10 opioid exposure and pediatric chronic
11 conditions, the rate of chronic conditions was
12 high among all children" -- emphasis line on
13 all -- "in our study. Our results point to the
14 multifaceted nature of exposures including
15 substance abuse, poverty, and social
16 circumstances that shape the health of children
17 in Medicaid. Conclusion of article."

18 So, yes, this is one of those many
19 studies that I previously described it as being
20 unfortunately real world messy. So they were
21 not able to disassociate the exposure from all
22 of the other factors and rightfully acknowledge

1 that these other factors make that impossible,
2 but of course, these other factors of
3 themselves can lead to deleterious
4 consequences.

5 Q. Okay. However, the study did find
6 that the opioid exposed children at the highest
7 levels, correct?

8 MR. EHSAN: Object to the form.

9 THE WITNESS: Yes. In the sense
10 that the authors clearly state and conclude in
11 what I just read is that, A is true and B is
12 true and it is impossible to say that B is
13 caused by A because of C, D, E, F, and G that
14 all independently lead to, on a population
15 base, more complicated outcomes.

16 BY MR. BILEK:

17 Q. So this study doesn't trouble you?

18 MR. EHSAN: Object to the form.

19 THE WITNESS: I don't know what you
20 mean by "trouble" me.

21 BY MR. BILEK:

22 Q. Cause you concern that there could

1 be long-term problems resulting from opioid
2 NAS?

3 MR. EHSAN: Object to the form.

4 THE WITNESS: So this study of
5 itself is -- says that, gee, that is a
6 possibility. Doesn't seem like it's a
7 likelihood.

8 So in medicine, we rarely rely on
9 one study. We rely on the totality of the
10 literature, and I have already several times
11 given you the summation of the totality of the
12 literature, so no, I am not troubled at all.

13 BY MR. BILEK:

14 Q. Okay. Let's go to Exhibit 15 -- I
15 mean, 17.

16 (Deposition Exhibit 17 was marked
17 for identification.)

18 THE WITNESS: You have a lot of
19 exhibits here.

20 BY MR. BILEK:

21 Q. I have a lot.

22 A. I have a lot of clarifications for

1 any statements that are oversimplified.

2 I have Item 17 in front of me.

3 Q. Okay. Can you identify Plaintiff's
4 Exhibit 17?

5 A. An article in the Journal of
6 Pediatrics from 2018 entitled: "Educational
7 Disabilities Among Children Born With Neonatal
8 Abstinence Syndrome."

9 Q. Have you reviewed this study before?

10 A. I don't recall if this is one of the
11 specific ones I reviewed or not.

12 Q. Okay. So in this, going to the
13 background, it says: "Neonatal abstinence
14 syndrome is a prenatal drug withdrawal
15 syndrome" --

16 A. It doesn't say that. It doesn't say
17 that.

18 Q. A post-natal. How did I do? Well,
19 I will just have you read. Why am I reading
20 for? You're a better reader than I am. I'm
21 sure you'll say that.

22 A. I don't know about better, but I

1 striving to be accurate. "Neonatal Abstinence
2 Syndrome, NAS, is a post-natal drug withdrawal
3 syndrome that can occur after intrauterine
4 opioid exposure."

5 Q. "Adverse neural behavior outcomes
6 have been documented in infants with NAS."

7 Do you see that?

8 A. Yes. After that comes a semicolon,
9 to continue their thought: "However,
10 educational outcomes have not been thoroughly
11 examined. We analyzed Tennessee data to
12 understand the need for special educational
13 services among children who are born with NAS."

14 Q. Seems like something that could be
15 studied, right?

16 MR. EHSAN: Object to the form.

17 THE WITNESS: Actually, it's a good
18 demonstration, this article, of why the current
19 practices of follow-up are so important. So
20 since you read and I read the statements in the
21 abstract that begin under background, let me
22 read the briefer part that comes under

1 conclusions: "Results of this novel analysis"
2 -- you know, it's novel in that it was in
3 Tennessee, but -- "results of this novel
4 analysis linking health and education data
5 revealed that children with a history of NAS
6 were significantly more likely to have a
7 subsequent educational disability."

8 Now, as I am reading this, I am
9 remembering more about this article, which yes,
10 I have reviewed, and what this article shows is
11 that the population they studied were Medicaid
12 in Tennessee. They were as you had previously
13 described, vulnerable populations.

14 These were babies who did not have
15 purely NAS. They had a history of NAS. They
16 also had all of those other aspects, you know,
17 that put them at disadvantage. And, hence,
18 that is why these kids are followed not only
19 with routine pediatric care but they are
20 followed by social services, behavioral
21 services, other services, sometimes legal
22 intervention, depends on the place.

1 BY MR. BILEK:

2 Q. So, but the question that was being
3 posed here was whether the opioid-exposed
4 children had more serious problems, long-term
5 problems, educational problems, right?

6 MR. EHSAN: Object to the form.

7 THE WITNESS: No. That wasn't the
8 question they posed, or not specifically the
9 question they posed. They did an analysis
10 linking health and education data to see what
11 came out. They didn't have a prior conception
12 I would not think.

13 BY MR. BILEK:

14 Q. Let's just go to the next page when
15 it says what they are trying to do. And it's
16 the next big full paragraph that says: "The
17 Tennessee Department of Health received
18 anecdotal reports from educators in Tennessee
19 that children with a history of NAS had greater
20 learning challenges and behavioral difficulties
21 in the classroom."

22 Do you see that?

1 A. Yes.

2 Q. So and if you go to the next
3 paragraph, it goes -- I mean, under:
4 "Methods," they talk about that there are
5 differences, and the study is being set up to
6 try to match and determine whether same
7 economic circumstances, same family
8 circumstances of the child made a difference of
9 whether or not the child had NAS as far as the
10 outcome.

11 MR. EHSAN: Object to the form.

12 BY MR. BILEK:

13 Q. Would you agree that that is a fair
14 characterization of what the study is trying to
15 do?

16 MR. EHSAN: Same objection.

17 THE WITNESS: Yeah. I need to read
18 what they actually said versus your synopsis to
19 be careful about that.

20 BY MR. BILEK:

21 Q. If you need to refamiliarize
22 yourself with this study, I am more than happy

1 to go off the record and take a break and you
2 can read it again.

3 A. Let me read it briefly while we are
4 still on.

5 MR. EHSAN: Just for the record,
6 Tom, you put an exhibit in front of him. You
7 are asking him questions. He is entitled to
8 read it, and that should go on the record. If
9 you want to call the magistrate, we are happy
10 to call the magistrate, but you are not
11 entitled to force him to read documents you put
12 in front of him off the record.

13 MR. BILEK: Well, this is a study
14 that he put in his -- that he had reviewed.

15 MR. EHSAN: It doesn't matter.

16 MR. BILEK: We will do that but this
17 has been one of the most obstreperous witnesses
18 I have ever met. But besides that, let's just
19 realize that this study does not say what he is
20 saying. I mean, no one could read this study
21 what he is doing. But let's go off.

22 THE WITNESS: I have not said what

1 the study says. You have said what the study
2 says, and I said I need to read it for myself.
3 I am not being obstreperous. I am trying to
4 get around vague, meandering questions.

5 MR. EHSAN: Dr. Rubin, just for the
6 benefit of moving things along, you don't need
7 to have a back and forth. Read it, answer his
8 questions. We can move on.

9 THE WITNESS: Thank you.

10 Okay. I have given it a fairly
11 quick once-through. Ask me your question,
12 please.

13 BY MR. BILEK:

14 Q. This shouldn't be a once-through for
15 you. You said you reviewed this before.

16 MR. EHSAN: Objection to the form.

17 THE WITNESS: If you want to quibble
18 with me, you are correct. I just reread it as
19 a once-through.

20 BY MR. BILEK:

21 Q. Okay. Now, the point of the study
22 was to try to figure out whether there was

1 difference between children with NAS, opioid
2 exposed children with NAS and those without NAS
3 in the same social circumstances. Isn't that
4 correct?

5 A. That is correct. That was the aim.

6 Q. They are trying to tease out social
7 circumstances, right?

8 A. That was the aim.

9 Q. And so that was the goal of this
10 study, and the conclusion of the study was that
11 NAS children needed -- fared worse than the
12 non-NAS children in the same economic
13 circumstances, correct?

14 A. I'm sorry, you said "needed, fared
15 worse." I don't understand.

16 Q. That the NAS children fared worse as
17 far as their educational disability. They had
18 more educational disability than non-NAS
19 children in the same social circumstances?

20 A. Yes. Separating the ones who
21 received a diagnosis of NAS from babies who
22 didn't, in the study, that was true.

1 MR. EHSAN: I object to the form.

2 Doctor, if you can give me one
3 second because of this lag, I have to wait to
4 make sure he is done before I can object, so
5 just give me one second. Thank you.

6 BY MR. BILEK:

7 Q. So does this study cause you any --
8 does it disturb you in any way that there may
9 be long-term additional problems for NAS
10 children versus children that are in the same
11 economic circumstance?

12 MR. EHSAN: Object to the form.

13 THE WITNESS: Does it disturb me?
14 I'm not sure how to answer that.

15 BY MR. BILEK:

16 Q. Yes.

17 A. But I will answer you about whether
18 I am disturbed by the quality of the
19 conclusions, and I am not, because to be a bit
20 more granular and accurate, let me just point
21 out several things that are said that are
22 alighted by, you know, the conclusion that you

1 are saying that they drew.

2 First of all, in terms of follow-up,
3 let me address Page 6, middle column, second
4 paragraph. It states: "In Tennessee, NAS is
5 an automatically qualifying diagnosis for early
6 intervention services. Early intervention
7 services are the precursor to special education
8 services for children under 3" -- blah blah
9 blah, and then later on on that same page, on
10 the right-hand column, second paragraph, about
11 five lines down: "However, best estimates are
12 that TennCare" -- that's the Tennessee Medicaid
13 program -- "provides services to approximately
14 90 percent of children who are born with NAS in
15 Tennessee."

16 So that's the first part about,
17 should -- you know, do they need further
18 monitoring? They are being further monitored.

19 Your next question is that you have
20 kept on saying what about, doesn't this show
21 the link to opioids and deleterious outcomes in
22 babies who had NAS.

1 So let me read you continuing from
2 where I just did: "NAS can occur after fetal
3 exposure to substances (benzodiazepines,
4 selective serotonin reuptake inhibitor and
5 alcohol) other than opioids and we were unable
6 to validate that all children with NAS in our
7 sample had in utero opioid exposure or confirm
8 that children without NAS did not have an in
9 utero opioid exposure."

10 Again, this is a paper that
11 illustrates the messiness of trying, especially
12 in a high-risk population, to sort these things
13 out. Which is why I keep coming back to, one
14 needs to read this literature critically and
15 thoroughly and also look at the papers that
16 more successfully can separate out the opioid
17 exposure per se. This was not designed nor did
18 it show that.

19 MR. BILEK: Well, I move to strike
20 -- I object to your answer as being
21 nonresponsive.

22 BY MR. BILEK:

1 Q. Now, let's go to the final paragraph
2 in the article to see whether you agree with
3 this or not.

4 A. Okay.

5 Q. It says: "Furthermore, children
6 with the history of NAS were more likely to be
7 diagnosed with educational disabilities in
8 development, delay in speech, language
9 impairments."

10 Do you agree or disagree with that
11 finding?

12 A. No, that is a true statement in
13 their study as far as it goes. With the
14 importance, and I am not being unresponsive, I
15 am clarifying the medical literature for you.
16 They were not able to define NAS as being due
17 to opioid exposure nor were they able to sort
18 out a bunch of the issues although they tried
19 about environment and those babies who had NAS.

20 Q. The final --

21 A. I applaud them for their attempt.

22 Q. Would you read the final sentence of

1 the report, please.

2 A. "These results further substantiate
3 the need for efforts to reduce intrauterine
4 opioid exposure and NAS."

5 Q. Do you agree with that?

6 A. Well, I agree with that in the
7 obvious way that illicit drug use and
8 self-medication with opioids should be -- as a
9 national policy, be decreased. That is not to
10 say that appropriately-prescribed opioids are
11 not very appropriate in specific situations
12 that I have previously referred to, so yeah, I
13 mean, how can you argue with that.

14 Q. Okay. I'll move to strike as
15 nonresponsive.

16 THE WITNESS: I'm sorry. Can you
17 repeat. I can't hear you and neither can the
18 reporter -- recorder.

19 BY MR. BILEK:

20 Q. The issue that I have is that, in
21 any event, you find that the flaws in the study
22 mean that this study doesn't disturb you or

1 cause you to believe that there are long-term
2 consequences as a result of opioid exposure.

3 A. You have no idea --

4 MR. EHSAN: Object to the form.

5 THE WITNESS: You have no idea what
6 disturbs me or doesn't disturb me. From a
7 professional point of view, this contributes to
8 me to the messiness of trying to sort these
9 issues out, which is why, as I have said
10 enumerable times, we need to look critically
11 and we need to look at studies that are able to
12 do this a little bit better depending on the
13 populations they are studying.

14 BY MR. BILEK:

15 Q. But so, let's go to Exhibit 16.

16 MR. BILEK: Can the court reporter
17 please hand him Exhibit 16.

18 (Deposition Exhibit 16 was marked
19 for identification.)

20 THE COURT REPORTER: 16, 1-6?

21 MR. BILEK: 16.

22 THE COURT REPORTER: Okay. Got it.

1 MR. BILEK: 1-6.

2 THE COURT REPORTER: 1-6. All
3 right. The witness has Exhibit 16.

4 BY MR. BILEK:

5 Q. Could you identify this document for
6 the record, please.

7 A. It is a paper from January 2020,
8 published in Journal of Autism and
9 Developmental Disorders entitled: "Brief
10 Report, Maternal Opioid Prescription From
11 Preconception Through Pregnancy and the Odds of
12 Autism Spectrum Disorder and Autism Features in
13 Children."

14 Q. Have you seen this before?

15 A. I don't recall.

16 Q. I will state to you that it is not
17 cited in your report.

18 A. Which is not identical to whether or
19 not I have seen it before.

20 Q. Okay. Well, maybe looking at it
21 will refresh your memory. Go to the abstract.

22 It says: "Opioid use during

1 pregnancy is associated with suboptimal
2 pregnancy outcomes. Little is known about
3 child neurodevelopment outcomes. We examined
4 the association between maternal opioid
5 prescriptions preconception to delivery.
6 During pregnancy and child's risk of ASD,
7 developmental delay disorder with no ASD
8 features or ASD DD with autism features in this
9 study to explore early development case
10 control. Study of neurodevelopment."

11 Does this refresh your recollection
12 at all of whether you have read this before?

13 A. No, it doesn't.

14 Q. Okay. "Pre-conception opioid
15 prescription was associated with 2.43 times the
16 odds of ASD, 95 percent confidence interval,
17 and 2.64 times the odds of ASD DD with autism
18 features compared to mothers without
19 prescriptions."

20 Do you see that?

21 A. Of course, I do.

22 MR. EHSAN: Tom, just one second.

1 Under Federal Rules of Evidence 106, I do think
2 that in terms of completeness, it would be
3 important to put in the confidence interval as
4 part of what you read because they're part of
5 the sentence.

6 BY MR. BILEK:

7 Q. Both of them are at 95 percent
8 confidence interval.

9 A. No. That is actually not true. I
10 will tell you what 95 percent confidence
11 interval means. It means the number, which is
12 not given here, and the range. And so the
13 range in the first one is .99 to 6.02 and in
14 the second one, it's 1.10 to 6.31.

15 Q. So you are having a problem with the
16 study. You are saying it's not scientific
17 because you are disagreeing with the confidence
18 measures?

19 MR. EHSAN: Objection.

20 THE WITNESS: Is there any way to --
21 I am asking this to all the attorneys. Is
22 there any way to prevent or I just deal with

1 it, words that are not mine being put into my
2 mouth?

3 BY MR. BILEK:

4 Q. I am asking you a question.

5 A. No, you were not.

6 Q. I don't have to repeat everything
7 that you say to me, sir, and really, you just
8 need to answer questions and not try to figure
9 out how you are going to help your client. You
10 just need to answer the questions truthfully
11 and honestly.

12 Do you understand that?

13 MR. EHSAN: I'm going to object to
14 that as argumentative, Tom. If you want to
15 call the magistrate for that, by all means, go
16 ahead.

17 THE WITNESS: You really are arguing
18 with me. What I said -- what I said --

19 BY MR. BILEK:

20 Q. Just answer the question.

21 MR. EHSAN: Just answer to the best
22 of your ability. Either answer the question or

1 tell Tom you don't understand the question.
2 That's the nature of the -- we don't need
3 commentary from anybody.

4 THE WITNESS: No. But what I need
5 to tell Tom is that that's not what I said,
6 that's not what I implied. What I did say is,
7 I read you what the confidence intervals was.
8 I didn't say scientific. I didn't say
9 nonscientific.

10 That first confidence interval means
11 it wasn't statistically significant in that
12 limited way and the other one means it's mildly
13 so.

14 But, frankly, I can't make any
15 comments about this paper without having the
16 ability to go and read through it.

17 BY MR. BILEK:

18 Q. Would you like to take a break and
19 read through it?

20 A. I see a cross --

21 MR. EHSAN: Again.

22 THE WITNESS: Sorry.

1 MR. EHSAN: Counsel, if we can have
2 him read it because you asked a specific
3 question, give him time to read it and ask your
4 question. Otherwise, you can move on. It's
5 your time. You can do it as you wish.

6 BY MR. BILEK:

7 Q. The big issue of this study that --
8 first of all, did -- this study came out this
9 very time that you were trying to write your
10 report that there were no long-term effects,
11 right?

12 MR. EHSAN: Object to the form.

13 THE WITNESS: I have said that -- I
14 mean, maybe. I have said that, I don't recall
15 whether I have seen this study among the
16 several hundred studies I've read on NAS. I
17 may have, I may not have. That's a separate
18 issue from my determination about the quality
19 of the study.

20 I can't address the quality of the
21 study or accept the conclusions of a study
22 unless I have read it. Simple. I am looking

1 across the table and I see a fairly large pile
2 of exhibits, many of which look like they are
3 articles. If we are going to go through every
4 single article and I need to take time to go
5 through the articles, we will be here for a
6 long time. I would need time to go through
7 this article. Just tell me what to do.

8 BY MR. BILEK:

9 Q. Okay. I will ask my question. You
10 can answer what you can.

11 Looking at the study right there,
12 based on the confidence intervals, is this some
13 study that you would not consider to be
14 scientifically reliable?

15 A. I cannot answer that --

16 MR. EHSAN: Object to the form.

17 THE WITNESS: -- without reading the
18 study. The abstract -- the abstract doesn't
19 tell you enough about the study. That's why
20 there is a paper following it.

21 BY MR. BILEK:

22 Q. Okay. The next question is: If the

1 study is scientifically reliable and is showing
2 that we have increased rates of autism with
3 opioid exposed children, that that would be a
4 concern to you, correct?

5 MR. EHSAN: Object to the form.

6 THE WITNESS: You know, yes, with a
7 necessary brief follow-up. I don't know
8 whether they were able to sort out the effect
9 of NAS from everything else. For one thing,
10 right in the abstract, it says it's a
11 comparison of babies born where women were
12 prescribed opioids versus women who were not
13 prescribed opioids. Those are not two
14 comparable groups necessarily. People are not
15 prescribed opioids for no reason. They are
16 prescribed for a reason, so I need to read it
17 critically to comment on it.

18 BY MR. BILEK:

19 Q. Well, let's look at it this way. At
20 this point, you are not willing to opine on
21 this study one way or the other.

22 A. Correct.

1 MR. EHSAN: Objection.

2 BY MR. BILEK:

3 Q. And it's fair to say that you didn't
4 consider this opinion in drafting your report.

5 A. Incorrect.

6 MR. EHSAN: Object to the form.

7 BY MR. BILEK:

8 Q. Well, you have no evidence that you
9 did.

10 A. You have no evidence that I didn't.
11 What I said is that I have -- you have got to
12 let me finish a brief -- you cut me off when I
13 try and answer you.

14 I am not being argumentative. I am
15 trying to finish a sentence. I realize that
16 Zoom makes everything much more difficult.

17 What I said is that, you can't, you
18 know, rule out that I didn't, simply because,
19 like I said, I have looked at an enormous
20 number of papers. I frankly offhand do not
21 recall one way or the other whether this is one
22 of them. Period. That's all.

1 MR. EHSAN: How about we take a
2 five-minute break whenever you are ready.

3 MR. BILEK: Okay. Fine by me.

4 MR. EHSAN: All right.

5 (A short recess was taken.)

6 MR. BILEK: Court Reporter, could
7 you hand Exhibit 19 to the witness, please.

8 (Deposition Exhibit 19 was marked
9 for identification.)

10 BY MR. BILEK:

11 Q. Can you identify this exhibit for
12 the record.

13 A. A publication in the journal, JAMA,
14 J-A-M-A, Network Open from 2019 entitled:
15 "Cognitive and Motor Outcomes of Children With
16 Prenatal Opioid Exposure, a Systematic Review
17 and Meta-Analysis."

18 Q. What is a meta-analysis?

19 A. So a meta-analysis is a technique by
20 which individual studies, in this case,
21 individual clinical trials usually are
22 aggregated. It's not a straightforward

1 process, but aggregated trying to control for
2 differences among the studies in order to try
3 and draw a conclusion that is based on the sum
4 of the studies.

5 Q. In order to -- in other words, to
6 get power from the number of studies, right?

7 A. In part.

8 Q. If you turn the page to the key
9 points. The first is the question: "Is
10 prenatal opioid exposure associated with
11 differences in childhood cognitive and motor
12 developments."

13 Do you see that?

14 A. I'm sorry. You said turn the page.
15 Which page?

16 Q. On mine, it's -- do you see the
17 question of the report?

18 A. Do you mean in the abstract?

19 Q. Yes.

20 A. Or on the key points?

21 MR. EHSAN: For me, it's on the
22 front page if that helps.

1 THE WITNESS: Yes. Key points.

2 BY MR. BILEK:

3 Q. On mine -- on my printout, it is
4 not, but whatever, it's on the front page.
5 It's where they do questions, findings,
6 meanings, right before the abstract.

7 A. I see it on my version.

8 Q. Okay. Now, the -- first of all,
9 have you reviewed this study?

10 A. It looks familiar. That's the most
11 I can say.

12 Q. I will represent to you it is not
13 cited in your report.

14 A. Okay.

15 Q. If that helps.

16 A. It doesn't. Sorry. It doesn't,
17 because I know I have read whatever is cited in
18 my report. I don't know offhand whether I have
19 read or not read other things. As I said, this
20 looks familiar.

21 Q. So in this study, it says -- the
22 question is: "Is prenatal opioid exposure

1 associated with difference in childhood
2 cognitive and motor development."

3 Do you see that?

4 A. Yes.

5 Q. And the finding in this systematic
6 review and meta-analysis of 26 studies, 1,455
7 children exposed to prenatal opioids compared
8 with unexposed children, prenatal opioid
9 exposure was associated with lower cognitive
10 scores, the largest difference was between ages
11 6 months and six years.

12 Do you see that?

13 A. Yes.

14 Q. Do you have a problem with this
15 finding?

16 A. I'm sorry.

17 MR. EHSAN: Object to the form.

18 THE WITNESS: Could you repeat it,
19 it got gabled.

20 BY MR. BILEK:

21 Q. The simple finding. Do you disagree
22 or have a problem with it?

1 A. With what?

2 Q. The finding.

3 A. The finding?

4 Q. It's just one finding, yeah.

5 A. Yeah. I don't know, because I need
6 to look at it critically to see, you know,
7 whether that, you know, to see what it's based
8 on.

9 Q. Okay. Well, we see 26 studies that
10 they compiled together.

11 Do you see that?

12 A. Yeah, that doesn't change what I
13 just said.

14 26 studies is nice. But what is the
15 quality of all of the 26 studies? You know, if
16 you put, you know, a pile of garbage and add 25
17 more piles of garbage to it, you have a larger
18 pile of garbage. I'm not saying that these are
19 garbage studies. I am merely saying that the
20 quality of studies throughout the literature
21 varies. I need to look at it in order to give
22 you my view on it.

1 Q. Well, is it fair to say that in
2 connection with your opinions in this case, you
3 didn't consider this study?

4 MR. EHSAN: Object to the form.

5 THE WITNESS: No. I have said, I
6 have said and I restated that I do not recall
7 whether or not I have read this study but it
8 does look familiar.

9 BY MR. BILEK:

10 Q. Okay.

11 A. I can't tell you more than that.

12 Q. Okay. So the -- the importance that
13 they say in the abstract was the: "Prenatal
14 opioid exposure, POE, is one of the
15 fastest-growing global health problems but its
16 association with long-term neurologic and
17 physical development remain unknown."

18 A. I'm sorry. Where are you reading?

19 Q. In the abstract under:
20 "Importance."

21 A. At the very top?

22 Q. Yes, sir.

1 A. Yes. So what you just read says:
2 "Prenatal opioid exposure, POE, is one of the
3 fastest-growing global health problems, but its
4 association with long-term neurological and
5 physical development remains unknown."

6 I would not agree with that in its
7 entirety. I would say there are some knowns
8 and some unknowns and I have given you the
9 reasons, you know, for that earlier by
10 discussing different issues in the medical
11 literature.

12 Q. So you go to the page -- mine is
13 printed out a little differently at
14 introduction.

15 Do you see that?

16 A. I'm in the introduction, yes.

17 Q. "Prenatal opioid exposure is a
18 fast-growing health problem, with at least one
19 in five pregnant women in high-income countries
20 known to have used some form of opioid during
21 pregnancy."

22 Do you see that?

1 A. I do.

2 Q. Isn't that an alarming number of
3 prescriptions to women that are pregnant?

4 MR. EHSAN: Object to the form.

5 THE WITNESS: Well, I don't know if
6 what you asked directly follows from that,
7 because it seems high to me, at least one in
8 five pregnant women in high-income countries.
9 I am looking at the reference to it.

10 The reference actually says:
11 "Prescription opioid epidemic and prenatal
12 outcomes."

13 It seems, you know, high to me, but
14 if that's what it states.

15 BY MR. BILEK:

16 Q. I mean, you don't have any evidence
17 to disagree with that number, do you?

18 A. I don't have any evidence to agree
19 or disagree. I, you know, must presume, it's
20 peer-reviewed so the reference must say that.
21 I need to look at the quality of the reference.

22 Q. In that same paragraph, it says:

1 "Neonatal abstinence syndrome affects 75
2 percent to 90 percent of all infants with POE
3 and it's considered a major global health
4 issue."

5 Do you have any reason to disagree
6 with that statement?

7 A. Not overall. I think it's difficult
8 to know whether it's truly 75 to 90 percent,
9 only because not all of the time when there is
10 opioid exposure is that known at the time when
11 the child delivers, and especially if the child
12 does not have NAS. It's not going to be
13 investigated.

14 Q. In any event, there is certainly a
15 high level of neonatal abstinence syndrome that
16 is being caused by POE; is that correct?

17 A. Yes. Prenatal opioid exposure is
18 one of the causes of NAS.

19 Q. Go down to the fourth paragraph
20 under the introduction.

21 It says: "Nevertheless, there is
22 increasing evidence that neurodevelopmental

1 surveillance and intervention for children with
2 POE should be as important as follow-ups for
3 children with other problems."

4 Do you see that?

5 A. Yes.

6 Q. Do you agree or disagree with that?

7 A. No, I agree. As I stated before,
8 it's important. I stated that in the context
9 of all of the services that currently are
10 geared.

11 Q. Let's go to the discussion. I can't
12 really tell you the page number because mine is
13 different from yours, but it's at the first
14 paragraph of the discussion.

15 A. Okay.

16 Q. So the sentence of: "Therefore, we
17 expect that up to 6.3 percent of children with
18 POE will have an IQ score of 2 SDs below normal
19 compared with 2.3 percent of children normally
20 distributed population, suggesting that
21 children with POE are three times more likely
22 to have severe intellectual disability,

1 according to the Diagnostic and Statistical
2 Manual of Mental Disorders, Fifth Edition,
3 material."

4 Do you see that?

5 A. I do.

6 MR. EHSAN: Object to the form.

7 BY MR. BILEK:

8 Q. Do you disagree with that finding?

9 A. I cannot agree --

10 MR. EHSAN: Object to the form.

11 THE WITNESS: Sorry. I cannot agree
12 or disagree without reading the body of the
13 paper. You are asking me to look at the
14 introduction, you are asking me to look at the
15 discussion.

16 The meat of the paper is actually
17 how the studies were done, so I need to look at
18 that in order to tease out in that sentence you
19 just read: "Therefore, we expect that up to
20 6.3 percent of children with POE with an IQ
21 score" -- da da da -- "suggesting that children
22 with POE are three times more likely to have

1 complications," and it goes on.

2 What I can't know without looking at
3 how they did it and what the quality of the
4 studies are or whether the POE, the prenatal
5 opioid exposure is merely, as it were, a marker
6 for all of the reasons why women during
7 pregnancy take opioids or whether it's due to
8 the drug itself.

9 And on that point, the sentence
10 after what you just read says: "This
11 difference is significant for children with POE
12 as they are already vulnerable given their
13 tenuous living circumstances and increased risk
14 of neglect and abuse, as well as their
15 propensity to have behavioral and attention
16 deficits, all of which contribute to poorer
17 academic, social and lifestyle outcomes."

18 So the crux is, how well were those
19 other things controlled for to be able to look
20 at the POE, again, the phrase per se. I don't
21 know.

22 BY MR. BILEK:

1 Q. I agree you don't know and that's my
2 point, Doctor. You didn't analyze this when
3 you wrote your opinion for \$40,000 that that
4 there are no long-term health consequences from
5 a child being exposed to opioids with NAS. You
6 didn't do that.

7 MR. EHSAN: Objection.

8 THE WITNESS: No. That is not a
9 true statement nor was it true the several
10 previous times when you said it. I will
11 reiterate for you.

12 What is cited in my report, I have
13 obviously read. What is not cited in my
14 report, I may have read or I may not have read,
15 but I will reiterate, I did a critical review
16 of the literature. My references are not meant
17 to be exhaustive. They are just illustrative,
18 as I said. I do -- this does look familiar to
19 me.

20 If there was the time, I would read
21 through the methods and results in this paper,
22 which is not a trivial thing in a meta-analysis

1 and be able to render a better opinion about
2 this particular paper.

3 What I continue to say is, I
4 reviewed a lot of the literature, a lot of the
5 literature is -- of the point I just mentioned
6 about in this paper, is messy. It's messy
7 because for real people in the real world, it's
8 difficult to sort out that fairly selected
9 group of people who -- where the fetus does
10 have a prenatal opioid exposure from all of the
11 reasons that they have that. That's all.

12 BY MR. BILEK:

13 Q. Let's look at it this way, Doctor.

14 How did you go about identifying
15 what documents you're going to tell me that you
16 had reviewed and which ones you didn't?

17 A. The studies that I reviewed at the
18 time when I wrote my report, and that I thought
19 were illustrative of particular points, there
20 are many points that don't relate to this
21 issue, I cited. You have been presented I
22 believe with a longer list of papers which is

1 -- which are papers that I utilized
2 contributing to my opinion. Doesn't -- as we
3 reviewed early in the morning, that's not the
4 same to say that those are the only papers I
5 have read, nor is it a legitimate conclusion
6 that because a paper is not listed, I don't
7 consider it to be helpful. I can't comment
8 further on this paper until I read it
9 critically.

10 Q. I am just asking you a different
11 question. If you just answer the question that
12 I am asking.

13 The question I am trying to get at
14 is: How did you determine what articles to say
15 that you relied on and what articles you said
16 you omitted from relying on? How did you
17 decide that?

18 MR. EHSAN: Object to the form.

19 THE WITNESS: I think all physicians
20 and certainly all academic physicians do or
21 should read the literature critically. Studies
22 that I thought were of sufficient quality, I

1 read and paid -- well, obviously read others
2 that I didn't think were of quality, that I
3 then utilized.

4 You know, many, but I certainly
5 couldn't say under testimony that every single
6 one of the studies that I -- that are listed
7 are ones that -- now I am losing my train of
8 thought. I'm sorry. I was looking at
9 something here. I can't say that that list is
10 absolutely exhaustive. I have read plenty of
11 other studies.

12 BY MR. BILEK:

13 Q. Let's look at it this way: Wouldn't
14 it be fair to state, Doctor, that what you did
15 in trying to determine to tell me what document
16 you relied on are the ones that you considered
17 to be important; is that correct?

18 A. You asked me --

19 MR. EHSAN: Object to the form.

20 THE WITNESS: You asked me if it's
21 fair, it's not fair. You asked me if it's
22 correct, it's not correct.

1 BY MR. BILEK:

2 Q. So are you going to provide -- I
3 mean, you understand, this is not your first
4 time you have been an expert witness, right?

5 A. Correct.

6 Q. And you understand you are under the
7 obligation to provide me with a list of all of
8 the documents that you have reviewed or relied
9 upon in connection with your opinion, correct?

10 A. Correct, and let me -- I'm sorry --
11 repeat something again. This particular
12 article, I would need to read or reread and do
13 that critically in order to determine whether
14 that was one that I had relied on or not relied
15 on. I can't answer that without, you know,
16 reading it critically.

17 Q. But this article certainly bears on
18 the issue of whether there are long-term
19 neurological problems with children that are
20 exposed to opioids in utero, correct?

21 A. Yes. In the sense that "bear on"
22 means that they approached that issue. I do

1 not know the quality of conclusions for the
2 link -- excuse me, or whether the link between
3 the diagnosis of NAS and these problems is
4 relatable to the causation of the opioid or
5 not.

6 Q. Going back to the sentence that you
7 were -- I thank you for reading that second
8 sentence, I think, could you agree that what
9 the authors are -- the point the authors are
10 trying to make is that many of the POE exposed
11 children are from low socioeconomic classes
12 that have extreme challenges already
13 confronting them without the opioid exposure?

14 A. Where are you referring back to
15 again?

16 Q. I am going back to the sentence you
17 read to me.

18 A. I know, but I closed the paper.
19 Please tell me where it is.

20 Q. It's discussion. We are on
21 discussion, first paragraph, last sentence.

22 A. Thank you. Okay. I have read it.

1 Q. Okay. Isn't the point that these
2 children are already disadvantaged before they
3 are being, you know, being -- added insult to
4 being exposed to opioids.

5 Wouldn't you agree this is a problem
6 that these mothers are already, most of them,
7 before we talk about disproportionate number of
8 them, are from very disadvantaged backgrounds?

9 A. Yes. But --

10 MR. EHSAN: Object to the form.

11 THE WITNESS: Yes. But in your
12 question you have the speculation in the term
13 "added insult."

14 BY MR. BILEK:

15 Q. You don't think that being exposed
16 by opioids in the womb is an added insult?

17 A. We spent quite a few hours looking
18 at that, not looking at that. I will again say
19 that the bulk of the literature for humans
20 looks as though -- in instances where there has
21 been prenatal opioid exposure, deleterious
22 consequences look like they are related to all

1 of these other vulnerabilities and not per se
2 to the opioid exposure.

3 Q. Of course, that is not what these
4 last studies have been saying, correct?

5 A. Oh, I don't know if that's the case
6 at all.

7 MR. EHSAN: Object to the form.

8 BY MR. BILEK:

9 Q. Okay. We will keep reading.
10 Let's go down to the next -- the
11 paragraph after the one that we just read the
12 sentence for.

13 It says: "Core neurodevelopment
14 outcomes in children with POE" --

15 A. Wait. Hold on. Hold on. I'm
16 sorry. Where in that paragraph are you? Oh,
17 that's two paragraphs down. I have got it.

18 Q. "Core neurodevelopment outcomes in
19 children with POE even from an early age is not
20 novel information."

21 Do you see that?

22 A. I do.

1 Q. Do you agree with that?

2 MR. EHSAN: Objection.

3 THE WITNESS: I cannot comment on
4 the quality of statements in this paper without
5 reading the paper critically, and when a broad
6 statement like that is made, seeing what the
7 references are. I am not agreeing nor am I
8 disagreeing.

9 BY MR. BILEK:

10 Q. Let's go to the conclusions. Are
11 you there?

12 A. Yes.

13 Q. Why don't you read the conclusions
14 into the record, please.

15 A. "The systematic review and
16 meta-analysis suggests that POE is negatively
17 associated with neuro-cognitive and motor
18 development."

19 Q. Read the whole paragraph, please.

20 A. "These differences begin from age 6
21 months and persist in adolescence. The exact
22 cause and the association of these findings

1 with clinical factors and environmental
2 adversities are unclear but suggest that
3 children with POE should be provided long-term
4 support and intervention beyond infancy."

5 Q. Do you agree with that?

6 A. Well, I agree with it to the extent
7 that the authors are acknowledging that they
8 can't tell whether the POE of itself or, as
9 they say, the other clinical factors and
10 environmental adversities are the cause. And
11 they also say long-term support and
12 intervention beyond infancy, which currently
13 does occur.

14 Another reason I need to read this
15 report is that, it's a decent journal that it's
16 in, but I note that the authors are a medical
17 student, The rest are entirely from Australia,
18 not to demean Australia at all. It's one
19 medical literature, but I don't -- it's not
20 clear to me what their areas of expertise are.
21 Certainly, they have areas of expertise in
22 doing a meta-analysis, but again --

1 Q. It's kind of like your question of
2 your expertise and whether you have any
3 expertise on long-term development of children
4 with respect to opioids.

5 You haven't published a single
6 article on that, have you?

7 MR. EHSAN: Object to the form.

8 THE WITNESS: Yeah. The answer is
9 that what I said is not like what you said at
10 all.

11 BY MR. BILEK:

12 Q. Okay. You would agree that there
13 are many experts in the world that have studied
14 the opioid as long-term -- the question of
15 long-term developmental problems.

16 A. Yes. And it's actually a point that
17 I made when you had asked about that because I
18 said there are many people who are doing it.

19 Q. And you are not one of those people?

20 A. Actively studying it, is that your
21 question?

22 Q. Yes, sir.

1 A. Currently, no.

2 Q. Have you ever studied it?

3 A. Not in humans, no.

4 Q. Well, okay. What animals have you
5 studied it in?

6 A. Well, doing reviews of animal
7 studies, not for opioids, not those animal
8 studies per se.

9 Q. Okay. You have reviewed some animal
10 studies, is that what you are saying?

11 A. Yeah. What I am saying is, I
12 legitimately hold myself out for having
13 expertise in NAS. The fact that I haven't
14 published a peer-reviewed paper in NAS,
15 although I have in these other areas is true,
16 but aside from the point.

17 I am not demeaning anybody else's
18 expertise. I am saying that I cannot comment
19 on work unless I have a chance to critically
20 review it. That's what I am saying. That's
21 all that I have been saying.

22 Q. Well, I heard you say that you were

1 criticizing these people in this peer-reviewed
2 literature because they hadn't -- you didn't
3 know what their expertise and I'll point out
4 you have got less expertise than probably these
5 doctors that are in the peer-reviewed article?

6 MR. EHSAN: Object to the form.

7 THE WITNESS: I have less expertise
8 than they probably do, almost undoubtedly, in
9 performing a meta-analysis, although I know how
10 to do one. I don't know what their expertise
11 is in the subtleties of neonatal abstinence
12 syndrome, but frankly, this is a rabbit hole
13 that is probably not taking us anywhere. I
14 cannot comment further about this study.
15 That's kind of where it ends.

16 BY MR. BILEK:

17 Q. Okay. Let's go to Exhibit 18.

18 MR. BILEK: Can you hand him Exhibit
19 18.

20 (Deposition Exhibit 18 was marked
21 for identification.)

22 THE COURT REPORTER: The witness has

1 Exhibit 18.

2 MR. EHSAN: Can I ask a question?
3 These exhibits, are they being marked as the
4 order in the way they're numbered or the way
5 they're being entered?

6 THE COURT REPORTER: The number that
7 they have -- the number he is asking is the
8 number they are marked as.

9 MR. EHSAN: Okay. So they are not
10 going to be sequential. We are going to be
11 missing exhibit numbers I presume.

12 THE COURT REPORTER: Possibly.

13 MR. BILEK: Exactly. So we can't do
14 it sequentially because we're -- depending on
15 which way he goes is which way he gets an
16 exhibit.

17 MR. EHSAN: Just want to clarify.
18 Because we're dealing with the Zoom thing for
19 the first time. I just wanted to clarify for
20 my own -- so if someone asked me why are you
21 missing exhibits, there are no missing exhibits
22 hopefully. It's just that the numbers skipped

1 around. Got it.

2 BY MR. BILEK:

3 Q. Doctor, can you identify Exhibit 18?

4 A. An article from 2020 in JAMA
5 Pediatrics. It's a letter. It's entitled --
6 it's actually June 2020: "Association of
7 Prenatal Opioid Exposure With Precentral
8 Gyrus" -- that's G-Y-R-U-S -- "Volume in
9 Children."

10 Q. Okay. JAMA, is that a prestigious
11 place to publish?

12 A. Well, it's JAMA Pediatrics.

13 Q. JAMA Pediatrics, is that someplace
14 that is fairly prestigious?

15 A. It's a highly-ranked journal.

16 MR. EHSAN: Object to the form.

17 BY MR. BILEK:

18 Q. The -- the -- first of all, what is
19 precentral gyrus volume in children?

20 A. It's referring to the volume of a
21 specific area in the brain.

22 Q. So what they were looking at is

1 whether the brain -- there is actual structural
2 brain differences in the opioid exposed
3 children, correct?

4 A. Correct.

5 Q. So the first sentence says:
6 "Prenatal opioid exposure associated with
7 delayed locomotor performance at multiple
8 stages of early child development and with
9 smaller neural anatomical structures such as
10 the basal ganglia."

11 See that first sentence?

12 A. Yes, I do.

13 Q. "The motor cortex which controls
14 speech and motor skills might also be
15 vulnerable to drug exposure. But to our
16 knowledge, is yet to be assessed. Identifying
17 risk of exposure associated with brain
18 structures is critical for prevention and
19 intervention strategies for cognitive effects
20 that can last longer after conception."

21 Do you see that?

22 A. Yes, I do.

1 Q. So first of all on Exhibit 18, have
2 you ever read this article before?

3 A. Looks familiar. I don't recall
4 specifically.

5 Q. This just came out -- let's see,
6 published June 8, 2020. Is JAMA Pediatrics
7 something you routinely read?

8 A. Articles in JAMA Pediatrics, I do
9 routinely read. New articles about NAS, I
10 read.

11 Q. So the issue here is -- going down
12 to the last paragraph. The last paragraph
13 after they say that opioids changed the brain
14 earlier.

15 A. I'm sorry. I'm sorry. Last
16 paragraph of what part of the paper?

17 Q. In the discussion. Last paragraph
18 before the footnote.

19 A. Okay.

20 Q. "Future research may investigate
21 whether medications for the treatment of opioid
22 use disorder, like buprenorphine" --

1 A. Close enough for present purposes.

2 Q. -- "and methadone, result in similar
3 brain changes and assess whether opioid
4 exposure has a dose-dependent dose."

5 And so the -- "has a dose-dependent
6 effect on gyri size, which was a limitation of
7 our study. In summary, these results suggest a
8 need for clinical screening for prenatal opioid
9 exposure during pregnancy and during the life
10 span as well as the reevaluation of risks and
11 benefits of prescription opioids during
12 pregnancy."

13 Do you see that?

14 A. Yes.

15 MR. EHSAN: Object to the form.

16 THE WITNESS: Thank you.

17 BY MR. BILEK:

18 Q. Do you agree with the last sentence:
19 "In summary, these results suggest a need"?

20 A. Well, there are several independent
21 clauses so let me go through them.

22 "These results suggest the need for

1 clinical screening for prenatal opioid exposure
2 during pregnancy."

3 Universal screening is not currently
4 recommended. That's taking the U.S. as an
5 aggregate, but the universal screening, meaning
6 screening every woman in pregnancy or a
7 pregnant woman when she shows up to deliver in
8 areas where prenatal opioid exposure is high or
9 just opioid rates are high, yes, that's just
10 done routinely.

11 I certainly don't disagree
12 particularly with that and during the life
13 span, I don't know what screening for prenatal
14 opioid exposure during the life span means
15 because it shows itself as NAS or not.

16 Then it goes: "As well as
17 reevaluating the risks and benefits of
18 prescription opioids during pregnancy."

19 Opioids are prescribed currently in
20 pregnancy for very strict reasons and trying to
21 give enough but not too much. And the further
22 characterizations of all of those things, we

1 discussed several hours ago, so I don't
2 disagree with that. I would just say it's
3 currently happening.

4 MR. BILEK: Do you want to take a
5 five-minute break before our next subject?
6 It's up to you.

7 THE WITNESS: No.

8 MR. EHSAN: Sure.

9 THE WITNESS: I would prefer to keep
10 on going unless you think we should take a
11 break.

12 MR. EHSAN: Okay.

13 MR. BILEK: Told by the witness.

14 THE WITNESS: Before we move on to
15 another subject, you didn't ask me in this
16 paper which is a letter, you didn't ask me the
17 question -- which is up to you -- the question
18 that you have asked about each of the other
19 papers having to do with the other conclusions,
20 and so I would just note that, you know, again,
21 I applaud the authors for trying to do this
22 type of research.

1 Volumetric, anatomic studies of
2 brain in living individuals is an exciting and
3 important area, but as I look at their methods
4 and results, I see again that in this article,
5 it is not possible to distinguish the
6 association of prenatal opioid exposure which
7 is what it states in the title, as something
8 that is potentially causative from all of the
9 other things that occur and the reasons why
10 people are prescribed opioids.

11 It's just a really, really important
12 point in this whole literature, and it is -- it
13 would lead toward mischaracterizations. I am
14 not saying you are making a
15 mischaracterization. It leads towards
16 mischaracterizations to look at somebody, a
17 baby, who has had prenatal opioid exposure and
18 so, oh, this problem that you have is due to
19 that, when there is so many other things that
20 can do that. That's all.

21 BY MR. BILEK:

22 Q. Okay. Want to take a short break or

1 go on to the next subject?

2 A. No. I'm done. Subject or break,
3 which one?

4 Q. That's totally up to you.

5 A. I'm fine with continuing.

6 Q. Okay. Let's continue.

7 The first question I have: The
8 consulting group that you are directly working
9 for is, I think is GLG, is that what you said?

10 A. That's what I said.

11 Q. Now, GLG, did you get authorization
12 from either your employer or Georgetown to work
13 for them?

14 A. No. I started working with them
15 before I came to Georgetown, and I don't do any
16 work with them nor frankly, any other
17 consulting during the time when I am doing my
18 full-time job. As a for instance, today is a
19 vacation day for me.

20 Q. Have you checked either GLG's
21 policies on that or Georgetown's?

22 A. I certainly read the information

1 from GLG whenever they first contacted me, and
2 when I joined the hospital in Georgetown, I
3 read their information. So I don't recall
4 anything that I saw that would preclude me
5 doing consulting work.

6 Q. Okay. First of all, what is
7 Frontiers in Pediatrics?

8 A. It's a journal.

9 Q. What kind of journal?

10 A. It's a medical journal.

11 Q. Do you -- is this something that you
12 work with?

13 MR. EHSAN: Object to the form.

14 THE WITNESS: By "work with," I am
15 one of the editors, and I -- as I can, I review
16 manuscripts for publication there.

17 BY MR. BILEK:

18 Q. And, in fact, I will stop beating
19 around the bush. You are an associate editor
20 of pediatric -- Frontiers in Pediatric, right?

21 A. I said I'm an editor. It's more
22 precise to say I am an associate editor.

1 Q. Okay. Now, do you get a salary for
2 that?

3 A. No.

4 Q. Okay. Would you agree that that's a
5 prestigious journal?

6 MR. EHSAN: Object to the form.

7 THE WITNESS: To my knowledge, its
8 rating has increased over the last several
9 years.

10 BY MR. BILEK:

11 Q. Is it a journal that you respect?

12 A. I'm sorry. Can you repeat that.

13 Q. Do you respect the journal in what
14 you are trying to do?

15 A. I mean, I don't respect or
16 disrespect it. It's a legitimate medical
17 journal, scientific journal, and I judge
18 articles in it either for my review before they
19 are published or when I read them after they
20 are published. I use the same criteria I use
21 with any article.

22 Q. And the -- we've already established

1 that you didn't disclose to Frontiers your
2 payments in this case, have you?

3 MR. EHSAN: Object to the form.

4 THE WITNESS: The thought never
5 occurred to me.

6 MR. BILEK: So could you hand the --
7 Court Reporter, could you hand the witness
8 Exhibit 25, please.

9 (Deposition Exhibit 25 was marked
10 for identification.)

11 THE COURT REPORTER: The witness has
12 Exhibit 25.

13 THE WITNESS: I have it.

14 BY MR. BILEK:

15 Q. I -- first of all, mainly, first,
16 get you to identify this.

17 Do you know -- the scope and mission
18 and policies there, do you recognize that?

19 A. Well, they look like the standard
20 sorts of scope, mission and policies for every
21 journal. I have to take your word from it that
22 these are the ones from Frontiers in

1 Pediatrics, yeah. I will assume that.

2 Q. Well, I will represent to you that
3 these are from the Frontiers in Pediatrics that
4 I took off the website.

5 A. Okay.

6 Q. The third paragraph says -- why
7 don't you read the third paragraph for me on
8 scope and mission?

9 A. "Frontiers" -- meaning the
10 journal -- "unique collaborative peer-review
11 process encourages authors, editors and
12 reviewer board members to join forces in
13 improving the quality of papers. Authors can
14 directly interact with reviewers in the
15 interactive review forum giving both authors
16 and reviewers the chance to exchange their
17 points of view in a productive dialogue.
18 Reviewers and editors are acknowledged on the
19 published paper giving authors an added level
20 of endorsement for their work. Frontiers also
21 employ a sophisticated social networking
22 platform loop for physician, scientists to

1 network, interact and to promote their work."

2 Q. Now, you would agree that this is a
3 good policy to have, right, it gives the
4 article a little more weight?

5 MR. EHSAN: Object to the form.

6 THE WITNESS: I don't really know
7 one way or the other whether it gives articles
8 a bit more weight. I think in the era of
9 online publishing, this is one of those
10 attempts to increase transparency in
11 interactions. I think it is a laudable goal
12 for myself, I find it unfortunately just
13 because I am not as computer savvy as I should
14 be, sometimes a little bit of a pain in the
15 butt to reviewing through this process, but I
16 admire the attempt at the process.

17 BY MR. BILEK:

18 Q. And one of the key points here is
19 that -- of the article, it adds another
20 endorsement to the article, correct?

21 A. That's what they say.

22 Q. Would you agree with that?

1 A. I think it's helpful to unblind
2 reviewers and editors to keep it a transparent
3 process, yes.

4 Q. Okay. Let's go to the second page:
5 "Associate editor assignment quality."

6 A. Excuse me. I'm sorry. Before we do
7 that actually, could I take a -- would you mind
8 if I took a bathroom break?

9 Q. No. No. You have to go through
10 these policies first.

11 A. I'm sorry.

12 Q. I just asked you five minutes before
13 whether you wanted to take a break, and you
14 didn't want to go. I understand this is
15 extremely -- going to be extremely
16 uncomfortable for you, but this is not the time
17 to talk to your lawyer.

18 A. First of all, that is an incorrect
19 assumption. Second of all, duty calls when
20 duty calls. I did not need to take a break
21 five minutes ago. I have been drinking a lot
22 of coffee and liquids. I do need to take a

1 break now.

2 The purpose of my break is to go to
3 the little boy's room, sir, not to consult with
4 attorneys. If you want me to sit here, I'll
5 sit here.

6 MR. EHSAN: If it makes you feel
7 better, Tom, I will stay within the scope of
8 your video.

9 MR. BILEK: I don't need you to
10 stay. We will take a five-minute break, and
11 agree that he is not going to talk to any
12 lawyers in the case.

13 MR. EHSAN: I will sit.

14 THE WITNESS: The only reason I
15 was --

16 MR. EHSAN: Go ahead, Doctor. Go
17 ahead and take your bathroom break. Please be
18 quick.

19 (A short recess was taken.)

20 BY MR. BILEK:

21 Q. "Associate editor assignment
22 quality."

1 A. Yes.

2 Q. Could you read Paragraph 2, please.

3 A. Read that? I'm sorry?

4 Q. Yes. Read that.

5 A. "Associate editors oversee the peer
6 review and make the final acceptance decision
7 on manuscripts. Editorial decision powers is
8 distributed in Frontiers because we believe
9 that many experts within a community should be
10 able to shape the direction of science for the
11 benefit of society."

12 Q. Again, you would agree that is a
13 laudable goal, correct?

14 A. Of course.

15 Q. Go to Paragraph 4:

16 A. "Associate" --

17 Q. Yes. Please read that.

18 A. "Associate editors are mandated to
19 only accept or edit a manuscript if they have
20 no conflicts of interest as stated here and in
21 their review invitation and" e-mail -- excuse
22 me -- "assignment e-mails."

1 Q. Now, would you say that if you are
2 getting paid by pharmaceutical companies, that
3 that would be considered a conflict of interest
4 with Frontiers' policy?

5 MR. EHSAN: Object to the form.

6 THE WITNESS: I have to answer that
7 by saying that I was retained to render an
8 expert summary, an expert opinion about
9 neonatal abstinence syndrome, not about drug
10 companies, not about anything else, neonatal
11 abstinence syndrome. That of itself has no --
12 a priority conflict with any of my unpaid
13 duties for Frontiers in Pediatrics.

14 BY MR. BILEK:

15 Q. So you are saying that the fact that
16 you are getting paid by pharmaceutical
17 companies is not going to be considered by
18 Frontiers as a conflict that must be disclosed?

19 MR. EHSAN: Object to the form.

20 BY MR. BILEK:

21 Q. That's what you are saying under
22 oath of perjury right now.

1 A. What I am saying under oath is --

2 MR. EHSAN: Same objection.

3 Argumentative.

4 MR. BILEK: It's not argumentative.

5 I want this witness to tell the truth.

6 THE WITNESS: You mean, as

7 opposed --

8 MR. EHSAN: Argumentative.

9 THE WITNESS: As opposed to
10 everything that I have been doing so far.

11 My conflicts of interest are
12 relevant conflicts of interest. I am not being
13 paid by a pharmaceutical company to do anything
14 specifically. I am not advising them or doing
15 anything else. I am rendering an opinion about
16 neonatal abstinence syndrome and the causes of
17 neonatal abstinence syndrome.

18 Nothing that I am doing here raises
19 any conflict to my -- I think pretty good
20 understanding about conflicts, financial and
21 otherwise, that would have to do with any of my
22 responsibilities reviewing papers here.

1 BY MR. BILEK:

2 Q. Sir, the issue is not whether merely
3 -- whether you are taking a position that you
4 consider is not relating to the drug companies
5 which I'm going to disagree with, but the issue
6 is, if you are getting money from drug
7 companies, you have to disclose it to Frontiers
8 under their policy, don't you, sir?

9 A. I would actually like you to point
10 that out to me because I don't know whether
11 that is true or not. I clearly need to point
12 out all of my consulting work above a certain
13 threshold to my employers, but I -- you haven't
14 shown me anything that says that I need or
15 don't need to report this to this journal.

16 If you show me something that says I
17 need to report it, darn tootin, I'll report it.

18 Q. So in this case, you understand that
19 your opinions are to help the drug companies,
20 right?

21 A. No.

22 MR. EHSAN: Object to the form.

1 BY MR. BILEK:

2 Q. Your opinion -- you're in opposition
3 to my clients who are the guardians of these
4 NAS children. You are filing a report that's
5 against their interest. You agree with that,
6 right?

7 MR. EHSAN: Object to the form.

8 THE WITNESS: No.

9 BY MR. BILEK:

10 Q. You don't think that this report is
11 going to be used by the drug company to try to
12 prevent recoveries by my client? Is that your
13 testimony?

14 MR. EHSAN: Object to the form.

15 THE WITNESS: Let me reiterate.

16 Because, you know, it's not that you are
17 accusing me but you are sort of implicitly, you
18 know, giving me purposes and goals that I don't
19 have. I was asked by -- you know, in effect,
20 four attorneys to write a report based on my
21 knowledge of neonatal abstinence syndrome.

22 That is exactly what I have done. I

1 have submitted my report, and I have discharged
2 that responsibility. I am not in control of
3 how that report then will be utilized,
4 misutilized, whatever, by anybody else. I
5 didn't write it.

6 BY MR. BILEK:

7 Q. We got the Nazi at the gas chamber,
8 right? I mean, I don't know what's going to
9 happen.

10 MR. EHSAN: Whoa, whoa, whoa, Tom.
11 Objection.

12 Court Reporter, could you please
13 mark that?

14 That, I am going to take up with the
15 magistrate because you just accused someone
16 of -- equivalent to being a Nazi and that is
17 unacceptable.

18 No -- court reporter -- no.

19 Bonnie, please mark that and
20 highlight it because that will go in the
21 Rule 11 motion against you, Tom. That is
22 uncalled for.

1 MR. BILEK: I apologize, and I
2 withdraw my comment.

3 THE WITNESS: I will --

4 MR. BILEK: My point is --

5 THE WITNESS: No. Let me say
6 something. I will accept your apology, but I'm
7 shocked that you would say that to me as
8 somebody who lost relatives, one and two
9 generations ago in the Holocaust. I'm kind of
10 appalled that you would say that.

11 My point is that -- no, no, no. Let
12 me finish. My point is that I wrote a report
13 that is a factual and evidence-based report. I
14 didn't write a supportive document leaning one
15 way or the other on any issue.

16 BY MR. BILEK:

17 Q. Okay. Well, let's go on.

18 A. I hope so.

19 Q. Whether or not you have the duty to
20 disclose payments from drug manufacturers, you
21 agree, you didn't disclose.

22 MR. EHSAN: Object to the form.

1 THE WITNESS: I adhered to my
2 understanding of Frontiers in Pediatrics. As I
3 read through that entire statement, and if you
4 go to the last page that you -- the second to
5 last page in what you photocopied, conflict of
6 interests are discussed on the following terms:
7 "Safeguards against financial conflicts of
8 interest."

9 And so under there, it says: "I
10 don't have the financial incentive to accept
11 articles, i.e., they are not paid for their
12 role to act as associate review editors and any
13 rewards gained is not linked to acceptances of
14 manuscripts."

15 I adhere to that. You asked me the
16 question. I'm answering it. I adhere to that
17 fully.

18 It then says: "Chief editors
19 receive an honorarium." I'm an associate
20 editor. I don't receive an honorarium. I
21 adhere to their conflict of interest policy.

22 BY MR. BILEK:

1 Q. Well, let's look at the other thing.
2 Have you looked at GRG's website -- GLG's
3 website of what they do as an expert witness?

4 A. No, not recently.

5 Q. I mean, one of the things that is on
6 the front line of it is: "Class certification,
7 retain experts to ensure or defeat class
8 certification."

9 Do you see that?

10 A. No, I don't see that. Of course I
11 don't see that.

12 Q. Right. But can you see?

13 A. This is frankly not going to be very
14 helpful.

15 MR. EHSAN: Doctor, I'm going to
16 object as this is an improper use of an exhibit
17 in a deposition under the federal rules, but go
18 ahead.

19 MR. BILEK: I will say that we just
20 got the GLG exhibits today and did not comply
21 with the subpoena, but in any event, I will
22 assume that --

1 BY MR. BILEK:

2 Q. Assume with me as a fact that on the
3 website says that the purpose is: "To retain
4 experts to ensure or defeat class
5 certification."

6 A. That's news to me, and because I
7 have looked at the GLG website, like a while
8 ago, this is the first time that a legal matter
9 was referred to me. It was not referred to me
10 as a class action, and frankly, whatever
11 statements GLG has about what their purposes
12 are are totally irrelevant to my actions on
13 deciding whether I would accept this
14 consultation and how I would go about doing
15 that.

16 So don't put GLG's, you know,
17 whatever GLG says, I don't work -- I'm not an
18 employee of GLG.

19 Q. So you don't work for GLG?

20 A. I am not an employee. Well, let's
21 say, I don't know if that's the exact meaning.
22 I did not review this for GLG and if I would

1 have, it would have been entirely irrelevant.
2 I am getting paid through GLG.

3 You have variously said I am paid by
4 a bunch of different entities but I am
5 certainly paid through GLG and I am paid for
6 doing a consultation with O'Melveny attorneys.
7 My purpose in that has never been to support or
8 not to support any entity in the legal
9 procedures.

10 I was asked to do a factual report
11 about three aspects of NAS. That's what I have
12 done.

13 Q. Okay. Now, let's go to --

14 MR. BILEK: Would you hand the
15 witness, please, Exhibit 26.

16 (Deposition Exhibit 26 was marked
17 for identification.)

18 THE COURT REPORTER: The witness has
19 Exhibit 26.

20 BY MR. BILEK:

21 Q. Can you identify Exhibit 26 for the
22 record, please.

1 A. Yes. It is an article published in
2 Frontiers in Pediatrics in June of 2020. It is
3 entitled: "Perinatal opioid exposure primes
4 the peripheral immune system towards
5 hyperreactivity."

6 I am listed as -- I am listed as the
7 editor. I did not review it. The reviewers
8 are listed, but I certainly looked at the
9 article, looked at the reviews, and I was the
10 editor.

11 Q. And you approved the article for
12 publication.

13 A. Yeah. That's the meaning of what I
14 just said.

15 MR. EHSAN: Object to the form.

16 BY MR. BILEK:

17 Q. Did you submit the article for
18 publication as editor?

19 MR. EHSAN: Object to the form.

20 THE WITNESS: No. I approved the
21 article for publication.

22 BY MR. BILEK:

1 Q. Did you think it should be published
2 in the Frontiers?

3 A. So it's a pretty obvious answer to
4 the question. If either the reviewers or I had
5 had significant problems with the revision of
6 the article, and this is the revision of the
7 article, I would not have agreed for the
8 publication or I would have taken myself off
9 being editor.

10 Q. And this -- one of the things that
11 the Frontier says the editor endorses the
12 article, correct, and you endorsed this
13 article?

14 A. I guess on the common meaning of
15 endorsement, yes, that's what I just said. I
16 approved of the article and I was willing to
17 have my name listed as the editor. Some people
18 like to do that frequently. I am not
19 particularly looking for articles to have
20 myself listed as the editor. I periodically
21 say yes to articles submitted to this journal.

22 Q. Well, Exhibit 26, you agreed to have

1 your name associated with this, correct?

2 A. Yeah, I think we covered this
3 ground, I'm sorry. Yes, yes.

4 Q. And reading -- and you are very
5 familiar with this article, right?

6 A. I'm pretty familiar with it.

7 Q. Okay. The first sentence says:
8 "The increased incidence of opioid use during
9 pregnancy warrants investigation to reveal the
10 impact of opioid exposure on the developing
11 fetus."

12 Do you see that?

13 A. Yes.

14 Q. Do you agree with that?

15 A. Yes. In the context of everything
16 else I have said today, that more research
17 about everything is a good thing.

18 Q. "Particularly evidence is mounting
19 that the developmental injury can result in
20 immune priming whereby subsequent immune
21 activation elicits an exaggerated immune
22 response."

1 Do you see that?

2 A. You started reading from someplace
3 that is not contiguous. Could you tell me
4 where you are reading from?

5 Q. I was just going -- let's just go
6 and have you read instead of me. The second
7 sentence. Please read the second sentence.

8 A. "Exposure during critical periods of
9 development could have enduring consequences
10 for affected individuals."

11 Q. And read the third sentence.

12 A. Okay. "Particularly evidence is
13 mounting that developmental injury can result
14 in immune priming."

15 Q. "Whereby subsequent immune activity
16 elicits an exaggerated immune response."

17 A. Oh, yes.

18 Q. What is -- what is your
19 understanding of what the authors and as
20 editor, you were trying to convey there?

21 A. I am not trying to convey anything.
22 The authors are trying to convey something, and

1 what they're summarizing is a very accurate
2 statement about the importance of, let's say,
3 neuroimmunology in terms of brain development,
4 an area with which I do have some expertise.

5 Q. Okay. And what is the -- what is
6 the issue with neural development with
7 immunology?

8 MR. EHSAN: Object to the form.

9 THE WITNESS: That's a pretty broad
10 question. They -- to try and answer that
11 relatively succinctly, the brain is not
12 entirely protected from the immune system.
13 There are immune regulatory cells in the brain.
14 They play important roles, not only in control
15 of immunity, but also in brain development and
16 brain function.

17 BY MR. BILEK:

18 Q. And interfering with that
19 development could have long-term consequences
20 for the individual, correct?

21 MR. EHSAN: Object to the form.

22 THE WITNESS: I don't understand the

1 question. You said "interfering with that
2 development."

3 What development are you referring
4 to?

5 BY MR. BILEK:

6 Q. Why are -- in this article, are they
7 looking at opioid exposure with the -- with the
8 peripheral immune system?

9 A. I'm sorry. I was asking you for
10 clarification on your previous question. You
11 are now asking me a different question. Do you
12 want to move on to that different question?

13 Q. Yes, sir.

14 A. Could you repeat that second
15 question.

16 Q. Why are the authors investigating
17 prenatal opioid exposure and its effects on the
18 peripheral immune system?

19 A. Well, I don't know their exact
20 motivations.

21 Q. What is your understanding as
22 editor?

1 A. That they have interests and some
2 expertise in areas of brain development, in
3 areas of immunology and, you know, this is
4 certainly a clinical scenario.

5 Q. Well, why is it important? What's
6 your understanding, why is it important? Why
7 are they doing this?

8 A. Well, I think you would need to ask
9 them why they do things rather than me. To me,
10 it is evident that they have chosen to look at
11 this for the reasons I just mentioned, and that
12 is an interesting question and I accepted being
13 the editor for.

14 Q. What -- let's go to the
15 introduction, second page, first sentence of
16 your edited article.

17 "The incidence of opioid abuse in
18 the United States has steadily increased since
19 2000 today reaching epidemic proportions."

20 Do you see that?

21 A. Yes.

22 Q. Is that a statement you would now

1 agree with?

2 MR. EHSAN: Object to the form.

3 THE WITNESS: Yes. It was
4 increasing before the year 2000 as well, but,
5 you know, that is not precluded by the
6 statement.

7 BY MR. BILEK:

8 Q. I am asking you, sir, do you agree
9 that it is reaching epidemic proportions?

10 A. It depends on the word -- their
11 interpretation of the word "epidemic." Opioid
12 use has been characterized as an epidemic.
13 Earlier today, you asked me about the opioid
14 crisis. I certainly agree with the fact that
15 opioid abuse has been increasing steadily in
16 the century. I try not to characterize that as
17 epidemic crisis or other terms that are less
18 precise.

19 Q. The crisis which you have -- "the
20 crisis is illustrated by data demonstrating
21 that the number of opioid-related
22 hospitalizations increased by 64 percent, the

1 number of deaths due to opioid overdose
2 increased by 27 percent between the years 2005
3 and 2014. Mirroring the national trends,
4 opioids used by pregnant women has escalated to
5 alarming rates."

6 Are you alarmed?

7 A. I'm sorry. What did you ask me? Am
8 I alarmed? I am --

9 Q. Yes.

10 A. You know, you've asked me if I am
11 alarmed. In the past, you have asked me other
12 things that are related to that. I am a
13 neonatologist who takes care, in part, of
14 babies with neonatal abstinence syndrome. That
15 distresses me. Of course.

16 Q. Well, of course you rely on --

17 THE COURT REPORTER: I'm sorry.
18 Could you repeat that question and speak up for
19 me.

20 BY MR. BILEK:

21 Q. "Mirroring the national trend,
22 opioid use by pregnant women has escalated to

1 alarming rates."

2 Do you agree with that?

3 A. Yes.

4 MR. EHSAN: Object to the form.

5 BY MR. BILEK:

6 Q. What?

7 A. Yes.

8 Q. You do? Okay.

9 Let's go to the second paragraph, go
10 to the middle. It says: "Recent studies
11 showing an association between opioid use
12 during pregnancy and poor health outcomes for
13 both pregnant women and infants highlight
14 prenatal opioid exposure as a serious public
15 health concern."

16 Do you see that?

17 A. I see everything that you are asking
18 me to look at, yes.

19 Q. Do you agree with that statement?

20 A. Sure.

21 Q. "Opioid exposed infants represent
22 extremely vulnerable patient population with 50

1 to 80 percent experienced neonatal abstinence
2 syndrome."

3 Do you see that?

4 A. Yes.

5 Q. Do you agree with that statement
6 that you edited?

7 A. Well, yes. In the same sense that
8 in terms of quantifying this, these are
9 ballparks. A previous article that you asked
10 me about a statement that I agree or disagree,
11 quoted 75 to 90 percent. Now it's 50 to
12 80 percent. Certainly it's the majority.
13 Difference in different populations.

14 Q. "The prenatal opioid exposures
15 associated with an increased risk of fetal
16 growth restriction, preterm birth, and lifelong
17 motor and cognitive deficits."

18 Do you see that?

19 A. I do.

20 Q. Do you now agree with that
21 statement?

22 A. I don't agree with all of the

1 implications of that statement, and here, I
2 should say something.

3 It was no conflict of interest for
4 me to agree to review a paper about prenatal
5 opioid exposure in Sprague Dawley rats, by the
6 way, at the same time as I had been retained to
7 write an expert report on neonatal abstinence
8 syndrome. I have expertise in neonatal
9 abstinence syndrome, I have expertise in
10 neurodevelopment.

11 But my own interpretation is that it
12 would have been a conflict of interest for me
13 to try and sway language that I may have
14 thought was a bit imprecise in the ways that I
15 have elaborated with other people's papers.

16 It would have been a conflict of
17 interest to me to have an agenda that, oh, by
18 the way, I have written an NAS report. It's a
19 legal proceeding, and it has to do with drug
20 companies being sued in some relationship with
21 neonatal abstinence syndrome, yes, it would
22 have been a conflict of interest to me to try

1 and make some of that language a little bit
2 more precise in the ways that I have elaborated
3 here today.

4 I had for myself two options. One
5 is I could say, gee, although I know a lot
6 about this topic, maybe I shouldn't review this
7 even though it's on rats, not humans. The
8 other is that I would look critically at the
9 methods and the conclusions, specifically the
10 methods and that I would leave it to the
11 reviewers to make comments as long as they
12 generally agreed with them about specific
13 wording.

14 So what I am trying to say is that,
15 yes, I'm the editor. Yes, my name is on here
16 and yes, I agree with this paper. But had I
17 been one of the reviewers, I might have
18 suggested a bit more qualification granularity.
19 I hope that clarifies my stance about this
20 paper.

21 Q. But you didn't, sir, did you?

22 A. I didn't what?

1 Q. When you weren't getting paid,
2 because you are not getting paid by Frontiers.
3 You didn't change -- you didn't suggest and
4 make any changes here, did you?

5 A. I don't understand what you just
6 asked me.

7 Q. I think you do, sir.

8 A. No. No. No. No. No. If -- no.
9 No. No.

10 If I understood what you asked me, I
11 would have said I understood. Please, so we
12 can get done, please don't tell me -- let me
13 finish a darn sentence. Please don't tell me
14 what I'm thinking.

15 I said I decided I had two choices.
16 One is I would say, gee, maybe this would be a
17 conflict. I just shouldn't review it, or I
18 would review this, you know, without any hat
19 on, that I had separately done the -- done on a
20 related topic, done in expert reports. I
21 decided to take what I considered to be the
22 high road.

1 Q. And this report that is being
2 published and peer-reviewed that you were the
3 editor is the truth, sir, right?

4 MR. EHSAN: Objection to form.

5 THE WITNESS: I'm sorry. What
6 report are you talking about?

7 BY MR. BILEK:

8 Q. These are things that you agreed
9 with in connection when you were editor?

10 A. I've already said yes.

11 MR. EHSAN: Objection.

12 THE WITNESS: I have already said
13 yes, and I've already said, but I will repeat
14 it, that I -- is that a given sentence may or
15 may not totally agree with my opinion. But in
16 general, it does.

17 BY MR. BILEK:

18 Q. Now, you didn't disclose this report
19 to your lawyers, did you?

20 MR. EHSAN: Object to the form.
21 Same objection.

22 THE WITNESS: It's published in

1 June. I reviewed this in the late spring, and
2 I don't recall offhand whether I mentioned it
3 or not.

4 BY MR. BILEK:

5 Q. Certainly, it isn't in your report
6 and you have not listed this as something that
7 you have told your lawyers that -- to tell me
8 that you reviewed or relied on this report?

9 A. I haven't lied about anything. I
10 resent that.

11 Q. I said "relied." I said "relied."

12 A. Pardon me. Okay. Darn Zoom.

13 I did not cite this report -- excuse
14 me, this paper in my report for the same reason
15 that I did not cite any animal studies in my
16 report. This is an animal study.

17 Q. You know, Doctor, an interesting
18 point, because when you did your one article on
19 opioids, you said in 1998, you were disturbed
20 by the size of the animal studies, correct?

21 A. Yeah. We went through that at that
22 point.

1 Q. Yeah. And so now you are saying
2 that you are not disturbed by animal studies;
3 is that right?

4 A. No. As usual, unfortunately, it is
5 not correct. What I said is that I did not
6 cite any animal studies in my report. You are
7 drawing whatever conclusions you want from
8 that. It's a simple factual statement.

9 Q. So the point being that the studies
10 that -- on the long-term health effect that the
11 meta-analysis that we talked about, the many 26
12 different studies that have been done and
13 long-term health consequences for NAS children,
14 those you thought you would find to be
15 extremely important and valuable, wouldn't you?

16 MR. EHSAN: Object to the form.

17 THE WITNESS: No. In fact, the
18 result of your questioning me about the
19 meta-analysis is that I think it's pretty close
20 to word for word, I cannot comment one way or
21 the other without having the opportunity to
22 critically read this meta-analysis.

1 BY MR. BILEK:

2 Q. Let's go to the last sentence in
3 that same paragraph. Would you read that.

4 A. Which paragraph were we on again?

5 Q. We are on -- in the introduction, we
6 are on the second paragraph and start with:
7 "The devastating."

8 A. "The devastating consequences of
9 opioid exposure are the physical health and
10 developmental outcomes of exposed children
11 strengthen the need to advance scientific
12 understanding of the underpinnings of
13 opioid-induced neural injury and to advance
14 biomarker development of this patient
15 population."

16 Q. That's contrary to your written
17 report in this case, isn't it?

18 MR. EHSAN: Object to the form.

19 THE WITNESS: I don't know if it's
20 contrary. It's certainly divergent, and as I
21 read through this paper, I perhaps -- and here
22 is my speculation about my own motives: In

1 agreeing to edit this, I wanted to be, as it
2 were, chaster than Caesar's wife. I wanted to
3 avoid any even unintentional slanting that I
4 would do about imprecisions in language. So my
5 name is on it --

6 BY MR. BILEK:

7 Q. (Inaudible)

8 A. No, no. You've got to let me
9 finish. When I take a break, it's for the
10 reporter.

11 It is -- my name is on it but I
12 cannot here say that I agree with every single
13 word in the introduction. I much more
14 carefully reviewed the scientific methods and
15 the meat of the paper.

16 Q. This slanting that you are talking
17 about that you didn't want to get involved in,
18 that would be contrary to what you wanted to do
19 in your written report in this case?

20 A. You've got to repeat that question.
21 It's my fault.

22 Q. I am asking you whether that's

1 contrary to your position that you took in this
2 case in which you wrote a slanted report?

3 MR. EHSAN: Object to the form.

4 THE WITNESS: Yeah. If I could, I
5 would object to your saying that it's a slanted
6 report. I did not write a slanted report, and
7 I do not understand your question aside from
8 the attempt to impute my integrity.

9 BY MR. BILEK:

10 Q. Well, let's put it this way,
11 something we can agree on.

12 Many long-term studies that were
13 contrary to your position were omitted from the
14 report.

15 MR. EHSAN: Object to the form.

16 THE WITNESS: My report cites a
17 small number of papers which in each case were
18 meant to be illustrative of a given point. I
19 will say for the nth time, my references are
20 anything but comprehensive or all inclusive.
21 No conclusion should be drawn further than
22 that.

1 BY MR. BILEK:

2 Q. I think we are done with that.

3 This article that you edited, do you
4 think other medical professionals can and
5 should rely on this?

6 A. Rely on it --

7 MR. EHSAN: Object to the form.

8 THE WITNESS: Rely on it for what
9 purposes?

10 BY MR. BILEK:

11 Q. Any purpose. Should this be added
12 to the scientific literature that a scientist
13 in your field should rely on?

14 A. So perhaps I can and I do not mean
15 to be patronizing, perhaps I can educate you on
16 medical literature. In this sense.

17 In a scientific paper that is a
18 study like an animal study and you are smiling
19 when I'm saying this, I want to make sure you
20 understand. A scientific study that is an
21 animal study looking at certain aspects has
22 appended to it an introduction less so a

1 discussion.

2 The people that read this who are
3 clinicians and scientists focus on the
4 operative details which are the materials and
5 methods and the results. Attorneys for their
6 own purposes may focus on the introduction.

7 Q. Okay. So we will skip some more of
8 those introductions. I will leave that for the
9 jury or if you end up showing up at trial.

10 Do the health professionals pay
11 attention to discussion or is it only the
12 conclusion? Which part is important?

13 A. Well, that depends on the journal
14 and the journal's formats. I mean, ideally
15 everybody looking at a paper should look at it
16 thoroughly and look at all the sections. The
17 sections that are objective are the sections
18 with the findings from a scientific point of
19 view, that's where we really focus on.

20 The introduction is meant to tie it
21 into the broader medical literature and the
22 results in some journals but otherwise the

1 discussion and/or conclusions are meant to
2 derive from the actual science, you know,
3 laboratory results, but also the authors'
4 efforts to interpret and speculate. I hope
5 that answers the question.

6 Q. Let's go to Page 8 because you said
7 that the importance is the conclusion.

8 In fact, that paragraph starts at
9 the conclusion so I assume that's the
10 importance.

11 Would you read the next couple of
12 sentences there?

13 A. On Page 8?

14 MR. EHSAN: Object to the form.

15 BY MR. BILEK:

16 Q. Page 8: "In conclusion."

17 A. Which appears under the discussion
18 section. Okay. Which paragraph? Oh, yeah. I
19 see it.

20 Q. "In conclusion."

21 A. "In conclusion, we provide evidence
22 and support of the systemic inflammatory

1 response to perinatal opioid exposure
2 characterized by immune cell reprogramming and
3 priming."

4 Q. Continue reading.

5 A. "This evidence may, in part,
6 contribute to the neurological injury following
7 developmental opioid exposure characterized in
8 our previous preclinical study. The current
9 study and the treating investigations that link
10 developmental and neurological injuries
11 including cerebral palsy and Down syndrome with
12 underlying systemic inflammation resulting from
13 abnormal PBMC activity."

14 Q. Do you agree with that?

15 A. Agree with which aspects of it?

16 Q. The conclusion of the study you
17 edited.

18 A. Okay. The entirety of what I just
19 read? Yeah. I agree with their results. I am
20 interested in their connection of the
21 implications of the results to other separate
22 issues of neurodevelopment as they mention,

1 cerebral palsy and Down's syndrome, and I am
2 also cognizant of the ways in which rodent
3 animal models do and cannot relate to
4 particular aspects of human development.

5 Q. This conclusion that is in this
6 study that you edited is contrary to what the
7 opinions that you have put in your report to
8 me, correct?

9 A. Absolutely incorrect.

10 MR. EHSAN: Object to the form.

11 THE WITNESS: Absolutely incorrect.

12 BY MR. BILEK:

13 Q. Okay. So you are saying that this
14 is consistent?

15 A. No. I am saying that it doesn't --
16 well, I didn't say, but you are incorrect,
17 because this does not directly relate to the
18 specifics of my report. In my report, in terms
19 of outcomes, I limited myself to the human
20 literature as I previously said.

21 I did not include animal literature
22 and for a very important reason. That things

1 that occur in neurodevelopment, brain
2 development in rodents, sometimes turn out to
3 be relevant and sometimes turn out to be
4 totally irrelevant to the human condition.

5 This is a broader issue in medicine.
6 If even, you know, even a minority of, for
7 example, cancer drugs that have shown to be
8 incredibly effective in mice had any
9 effectiveness in humans, we would be much
10 farther along in chemotherapy. It's an
11 unfortunate state of affairs that mice or rats
12 aren't people.

13 Q. I don't even know how to respond to
14 that. Let's go back to the study.

15 So you would agree that this study
16 does have some -- if this study on -- the
17 animal study doesn't apply to humans, if it
18 translates to humans, this is an extremely
19 troubling finding.

20 MR. EHSAN: Object to the form.

21 THE WITNESS: I don't know if you
22 are too far away from your mic. I don't know

1 if it's the zoom. Some of what you say keeps
2 on being garbled. I'm sorry I, need to ask you
3 to repeat that one too.

4 BY MR. BILEK:

5 Q. I'm sorry. Does the fact that this
6 study had animal studies, if it does translate
7 to humans, if it does work in the same manner
8 in the humans, would you agree that this is a
9 very disturbing and troubling development for
10 the children, long-term prognosis?

11 MR. EHSAN: Object to the form.

12 THE WITNESS: Unfortunately, not
13 necessarily, because of the previous reasons.
14 It's very difficult to take that leap from
15 brain development and for that matter, in
16 neuroimmunology from rodent models to humans.
17 I think, you know, we don't have enough
18 evidence about neuroinflammation in general in
19 people or young children, and we certainly
20 don't have enough information in terms of the
21 way that different factors that lead towards
22 NAS, including but not restricted to opiate

1 use, also including all of the other groups of
2 drugs that do cause NAS.

3 We don't have enough data on those.
4 When I say we don't have enough data on those,
5 again, obviously, people are not rats, people
6 are not mice. Really hard noninvasively to get
7 ahold of those kind of data.

8 BY MR. BILEK:

9 Q. These authors raised the red flags
10 that the opioid exposure could be a
11 contributing cause for Down's syndrome and
12 cerebral palsy, correct?

13 A. No. That's incorrect. You roll
14 your eyes at me, sir, but when you say that
15 opioid use can contribute to Down syndrome, I
16 should be the one rolling my eyes. No. That
17 makes no sense.

18 Q. Okay. Opioid exposed -- exposure
19 that leads to an NAS baby, that level of opioid
20 exposure could possibly cause permanent brain
21 injury including leading to cerebral palsy or
22 to Down syndrome, and that -- if this animal

1 study translates to humans, this is something
2 that should be studied, shouldn't it?

3 A. Yeah --

4 MR. EHSAN: Object to the form.

5 THE WITNESS: If you think that
6 exposure to opioids can cause Down syndrome,
7 correcting that view will take longer than we
8 have. It's an absurd proposition. The
9 question of brain injury and opioid exposure in
10 humans, I have addressed. The critical reading
11 of the literature is that to the extent we can
12 parse out all of the other really contributory
13 factors, there are no convincing data that
14 exposure to an opioid in utero per se causes
15 long-term neurodevelopment.

16 I wish I recorded that statement
17 because in the transcript, I can't even imagine
18 how many times I will have said that in that
19 way.

20 BY MR. BILEK:

21 Q. Let me go at it this way. Who told
22 you that that statement of yours that you

1 needed to parse that out, who told you that was
2 important?

3 A. Why do you assume that anybody told
4 me that was important?

5 Q. Is that what you told O'Melveny when
6 they contacted you to be an expert witness?

7 MR. EHSAN: Object to the form.

8 THE WITNESS: No.

9 BY MR. BILEK:

10 Q. When did you first tell O'Melveny
11 Myers about your opinion on that?

12 A. I filed my report. That has my
13 opinions. That is the first time that the
14 attorneys saw my opinions.

15 Q. So they had no idea of your opinions
16 prior to your report? Is that your testimony?

17 A. Yeah. To my knowledge, that's
18 absolutely true.

19 MR. EHSAN: Objection.

20 THE WITNESS: Because the -- no, no.
21 Because the implication is that I was coached
22 or that I am a hired gun or something else that

1 you have danced around during this time. You
2 don't know me. My reputation stands. I am
3 none of those things and I never have been.

4 I was asked to address specific
5 aspects of neonatal abstinence syndrome. I
6 have, to the best of my ability and to the best
7 of my ability, I am trying to answer your
8 questions.

9 BY MR. BILEK:

10 Q. Now, this is the authors' first
11 study as we've discussed, and in the
12 discussion, the second paragraph --

13 A. Hold on. Hold on. Sorry. In the
14 discussion, the second paragraph, you mean Page
15 7?

16 Q. I think on Page 6. Page 6 --

17 A. Ah, yes.

18 Q. It says: "Discussion."

19 A. Okay.

20 Q. Second paragraph, read that first
21 sentence, please.

22 A. "Using the same model of perinatal

1 opioid exposure employed in the current study,
2 we previously provided evidence of
3 neuroinflammation, microstructural brain
4 injury, persistent cognitive defects, and
5 peripheral immune activation following
6 perinatal opioid exposure."

7 Q. So this study was confirming a
8 previous study that they did, correct?

9 MR. EHSAN: Object to the form.

10 THE WITNESS: This study confirms
11 and extends information about specific opioids.
12 In this case, it's Methadone. They were given
13 to Sprague Dawley rats, yes. And, you know
14 again, what we find out from animal models is
15 important for looking at humans.

16 I am -- I do not argue obviously
17 with their results. I find it to be very
18 speculative of how much application these
19 results will have to humans.

20 MR. BILEK: Let's take a break. We
21 are getting close to the end. Take a
22 five-minute break.

1 (A short recess was taken.)

2 BY MR. BILEK:

3 Q. In connection with Exhibit 26, did
4 you note what the -- whether or not the authors
5 had cited to human studies for the proposition
6 that there were long-term cognitive effects
7 stemming from opioid misuse by the mothers in
8 utero?

9 MR. EHSAN: Object to the form.

10 THE WITNESS: I have no idea what
11 Cuban study you are referring to.

12 BY MR. BILEK:

13 Q. The article that we have just been
14 discussing, the article in which you edited,
15 did they cite to human studies?

16 A. I'm sorry. It's Zoom. I thought
17 you said Cuban, as in the island, not human as
18 in us.

19 Now appreciating that, could you
20 repeat the question so I can understand. I'm
21 sorry. I am thinking Cuba and going why is he
22 asking me about Cuba.

1 Q. In support of the authors in 26,
2 cite to studies that for -- in support of the
3 proposition that there are long-term cognitive
4 effects of opioid use, correct? They have a
5 number of footnotes.

6 A. No, I'm not certain I would
7 characterize their statements in exactly that
8 way. But you would need to point out specific
9 statements so I could look at it. I am not
10 sure about your characterization of it. Just
11 show me what it is you are referring to.

12 Q. Do you have any information or not
13 whether or not the authors in that case cited
14 to long-term human studies?

15 A. They cite human studies. Again, the
16 characterization that you made to what those
17 studies say, I'm sorry, I can't take your word
18 for it. I need to see what context and what
19 studies they are referring to. It's a very
20 simple request.

21 Q. We can spend a bunch of time on
22 this, but I have already done a bunch of work

1 on this.

2 My question is: Do you know whether
3 you cited in your report any long-term health
4 studies that are cited in Exhibit 26?

5 MR. EHSAN: Object to the form.

6 THE WITNESS: Okay. Either that's
7 zoom again or you had changed topics on me and
8 I didn't realize.

9 Yes, I have cited human long-term
10 studies in my report, in my report.

11 BY MR. BILEK:

12 Q. The report that's in Exhibit 26.

13 A. Okay.

14 Q. Did you cite to any of their studies
15 that they cite to that there were long-term
16 cognitive problems?

17 MR. EHSAN: Objection.

18 THE WITNESS: You -- you know, I
19 don't know why you don't understand this, but
20 show me what you are referring to and I will
21 respond.

22 Offhand, I do not recall whether

1 their reference list has any overlap with the
2 illustrative references that I used in my
3 report, not this report.

4 BY MR. BILEK:

5 Q. I will go to another. Let's go to
6 March of Dimes. March of Dimes cited something
7 that you consulted for, right?

8 A. The March of Dimes is an
9 organization that I had for many years
10 contributed to and also sat on local and
11 regional boards for the March of Dimes in
12 different locations.

13 Q. And you would agree that the March
14 of Dimes is attempting to do laudable work to
15 assist kids, right?

16 A. Yes.

17 Q. And, in fact, you put the March of
18 Dimes on your resume, you're proud of your work
19 that you have done with the March of Dimes,
20 right?

21 A. I am proud of the work that I did
22 with the March of Dimes. The fact that I put

1 something down on my CV is not a measure of the
2 degree of pride I have. It is a measure of
3 being complete. Everything that I have done
4 aside from side consulting on legal matters, I
5 have in my CV.

6 Q. So your CV, you do endeavor to be
7 complete?

8 A. I think as you probably realize, I
9 endeavor to be complete about everything.

10 Q. And the illustrative that you talk
11 about with the articles would just be --

12 MR. BILEK: Let's talk about Exhibit
13 27.

14 (Deposition Exhibit 27 was marked
15 for identification.)

16 THE COURT REPORTER: The witness has
17 Exhibit 27.

18 THE WITNESS: Exhibit 27 is a --
19 looks like a photocopy of either a flier or
20 something online that has the March of Dimes
21 logo and the title is: "Caring for a baby with
22 NAS."

1 BY MR. BILEK:

2 Q. Is this something that you have seen
3 before?

4 A. No.

5 Q. Were you involved at all with the
6 March of Dimes and their -- in connection with
7 NAS?

8 A. Yes, obviously.

9 Q. What did you do for the March of
10 Dimes in connection with NAS?

11 A. So as I -- you know, my involvement
12 with the March of Dimes goes back to the 1980s
13 and during that time, I was a participant,
14 fund-raiser, spokesperson, scientific and
15 clinical advisor and board member at different
16 times and in different places.

17 From many of those roles, I was
18 involved with their initiatives which as you
19 say are trying to improve the care and outcomes
20 of newborns and infants. The March of Dimes, I
21 should add, started under FDR's administration
22 and it were the dimes that were placed in order

1 to raise money for prevention of polio.

2 In subsequent years, the March of
3 Dimes began to refocus on important problems of
4 birth defects and more recently on prematurity,
5 and they deal with all sorts of newborn
6 problems which include NAS. I have spoken
7 with, I have lectured to March of Dimes people
8 about NAS at different times and in different
9 places, and finally, of course, which you will
10 bring up, but we previously -- and we
11 previously discussed, I was co-chair on an
12 initiative about NAS in Florida, and my
13 involvement was initially through being a board
14 member on the March of Dimes.

15 Q. And you said that initiative had to
16 do with NAS?

17 A. I'm sorry?

18 Q. Your initiative in Florida with the
19 March of Dimes?

20 A. Yes, what about it?

21 Q. Did it have to do with NAS?

22 A. Yeah, it was called the NAS

1 initiative.

2 Q. And what was the goal of the NAS
3 initiative in Florida?

4 A. I'm sorry. I know the hour is late.
5 You had asked me this whole line of questioning
6 in the first hour of this deposition, and I
7 explained to you in detail what I did,
8 including the fact that we provided no written
9 report and -- nor specific recommendations but
10 mostly fact-finding and education.

11 Q. Okay. That is my mistake. I didn't
12 realize that is what you were referring to.

13 Could you turn to Exhibit 27?

14 A. It's only one page. I have turned
15 to it.

16 Q. You got it. We are getting close.
17 If you will go down to the paragraph
18 that says: "As they grow older." Could you
19 read that?

20 A. I'm sorry. Could you say that
21 again. The paragraph that starts?

22 Q. Go down to the middle of the page

1 right above the box: "As they grow older."

2 A. "As they grow older." Okay. "As
3 they grow older, children who had NAS may have
4 problems with speech, language and learning."

5 Q. Continue.

6 A. "They may need early intervention
7 services to help them learn to walk, talk and
8 interact with others."

9 Q. Do you agree with this statement by
10 the March of Dimes?

11 MR. EHSAN: Object to the form.

12 THE WITNESS: Well, I never did and
13 certainly now, I don't speak for the March of
14 Dimes. I would say that strictly speaking, I
15 agree with the following sentence: "As they
16 grow older, children who had NAS may have
17 problems with speech, language and learning."
18 I agree with that and I have given you my --
19 again, critical reading of the literature,
20 which is that, yes, NAS is a marker, and there
21 are many ways of getting to NAS.

22 NAS may mean -- may be a consequence

1 of exposure to benzodiazepines, a group of
2 drugs called SSRIs, a variety of other drugs
3 but certainly also to opiates, and problems
4 that speech, language, learning have been
5 largely attributable to the circumstances that
6 underlie women using opioids, or for that
7 matter, polypharmacy, so yes, it's not a
8 causative statement but I agree with it.

9 The second statement, second
10 sentence: "They may need early intervention
11 services," exactly. These are high-risk babies
12 in vulnerable families. That's why we always
13 try and make sure that they have early
14 intervention services.

15 MR. BILEK: I pass the witness.

16 EXAMINATION BY COUNSEL FOR DEFENDANTS

17 JOHNSON & JOHNSON AND JANSSEN

18 BY MR. EHSAN:

19 Q. Dr. Rubin, realizing the time is
20 short, I will be quick.

21 Just starting with a point that was
22 made earlier, I think -- just want to ask you a

1 couple of questions.

2 One is, does maternal opioid use or
3 fetal exposure to opioid mean that the baby
4 will develop NAS?

5 A. No, and for example, in two of the
6 studies that I was presented with today, of
7 which I am familiar, one said 75 to 90 percent,
8 one said 50 to something percent.

9 So yes, many, but by no means all.
10 As I previously stated, not all babies who
11 receive a diagnosis of NAS have had
12 intrauterine opioid exposure and not all
13 newborns where there was neonatal opioid
14 exposure exhibited NAS.

15 Q. Doctor, my question was more basic
16 so I'm going to try to break down your answer.

17 First question, and just focusing on
18 my question: Does exposure by a fetus to an
19 opioid mean that that baby will develop NAS?

20 A. No. It increases the risk.

21 Q. Does the fact that a baby has a
22 diagnosis of NAS mean that baby was exposed as

1 a fetus to opioids?

2 A. Sometimes, but not all of the time.

3 Q. Doctor, turning your attention to
4 exhibit -- it is No. 19, I believe.

5 A. Yes.

6 Q. Let me make sure I am not
7 misrepresenting that number. You have to bear
8 with me a second. I am dealing with the
9 technological gaps here.

10 A. We need people who are 21 or
11 younger.

12 Q. I think I need a faster computer. I
13 will make the pitch for it.

14 Yes, Exhibit 19, Doctor, this is a
15 study by Su Lynn Yeoh and I might be butchering
16 the name in JAMA Network Open.

17 Do you see that one?

18 A. Yes, the systematic review and
19 meta-analysis.

20 Q. Yes. Do you recall being asked a
21 series of questions about this article?

22 A. I certainly do.

1 Q. Do you recall telling counsel that
2 you needed to critically evaluate the paper?

3 A. Yes, several times.

4 Q. If you go to page, at least on my
5 screen, paginated as 10 of 14, where the
6 conclusion is?

7 A. Yes.

8 Q. You were shown this conclusion.
9 Do you recall that?

10 A. Yes.

11 Q. If you just go immediately above,
12 what is the title of the immediate preceding
13 section?

14 A. "Limitations."

15 Q. And just reading the first sentence
16 for the record, please, Doctor?

17 A. "This meta-analysis has
18 limitations."

19 Q. And is it your understanding, and if
20 you need to read it to answer my question, by
21 all means, read it, but does that indicate to
22 you that the authors identified the limitations

1 of their study?

2 A. Well, it's certainly means that they
3 understood that there are certain limitations.
4 I'd need to read it to see if I can see other
5 limitations, typically all of us write that
6 there are limitations because there are in any
7 given study.

8 Q. Let me focus your attention on the
9 third paragraph that begins: "A key
10 limitation."

11 Do you see that?

12 A. Yes.

13 Q. Could you read that sentence.

14 A. "A key limitation is that we were
15 unable to contact some authors for missing data
16 resulting in the exclusion of studies without
17 means and standard deviations. We also had" --

18 Q. And the next sentence.

19 A. "We also had incomplete information
20 on rates of NAS, rates of foster care, sex,
21 parental education levels and substances used
22 in pregnancy. In addition" --

1 Q. You can --

2 A. Okay.

3 Q. You can stop, Doctor.

4 So would these limitations that the
5 authors identify be relevant to interpreting
6 the results?

7 A. Well, they are critical for
8 interpreting the results. It's the entire
9 reason why I said, for instance, and when
10 questioned about this article, is that I need
11 to be able to look at the article in order to
12 see whether the prenatal opioid exposure and
13 its links to outcomes bears on the prenatal
14 exposure per se or that broader context, and I
15 just read what several of the limitations are.

16 You know, again, that is
17 unfortunately but understandably the state of
18 many studies that have shown that when there's
19 NAS or when there is opioid exposure but
20 ignoring all of the other important factors
21 that you know there is some link.

22 Q. Doctor, do you know how many

1 articles would come up as a result, if you were
2 to search neonatal abstinence syndrome in
3 PubMed which is the National Institutes of
4 Health medical library?

5 A. Yeah, I actually did this a few
6 weeks ago. It was somewhere around 2,000, plus
7 or minus a few.

8 Q. Okay. So Doctor, is it fair to say
9 you did not cite 2,000 articles in your report?

10 A. That is a very fair statement.

11 Q. And your materials considered list
12 doesn't include 2,000 articles; is that
13 correct?

14 A. Absolutely not.

15 Q. Doctor, you said you read the report
16 of Dr. Anand; is that correct?

17 A. Yes, it is.

18 Q. And that report also included
19 citations, did it not?

20 A. Yes.

21 Q. Sitting here today, do you have a
22 recollection of whether Dr. Anand cited all

1 2,000 give or take articles related to NAS in
2 his report?

3 A. No, he certainly did not. I seem to
4 recall he had more citations than I had and a
5 longer page report than I had, but no, not a
6 lot more.

7 Q. Would it be fair to say that when
8 writing an article for a peer-reviewed
9 publication, that even if it's a review
10 article, one does not review the complete and
11 total publications available within the English
12 language assuming you are publishing it in
13 English?

14 A. That's certainly true.

15 Q. One last exhibit, Doctor, and this
16 is the next to last one you were shown.

17 This is Exhibit 26 on the Frontiers
18 in Pediatrics if you can put that in front of
19 you.

20 A. Yes.

21 Q. Now, Doctor, you recall just a short
22 while ago, you were asked a series of questions

1 about this article, correct?

2 A. Yes.

3 Q. And there was a series of questions
4 implying that opioid exposure, at least as the
5 authors noticed, or -- strike that.

6 Let me ask this question: There was
7 a suggestion that opioid exposure could lead to
8 Down's syndrome.

9 Do you recall that question and
10 answer?

11 A. That was a question that was posed
12 to me, yes.

13 Q. Now, Doctor, I'm going to attempt to
14 ask you a series of questions and I apologize
15 in advance for the level of detail for the
16 court reporter, but are you familiar with the
17 disease Down syndrome?

18 A. Extremely familiar.

19 Q. That is a genetic disorder; is that
20 correct?

21 A. Correct.

22 Q. And it results from having three

1 copies instead of two of Chromosome 21,
2 correct?

3 A. Yes.

4 Q. Does -- that genetic disorder occurs
5 at the moment the sperm actually fertilizes the
6 egg, correct?

7 A. Within a very brief period after
8 that.

9 Q. My apologies. So very shortly after
10 fertilization occurs, correct?

11 A. Yes. Just trying to be precise.

12 Q. So within the first or second
13 mitotic cycle, correct?

14 A. Thank you for saying that, yes.

15 Q. And I apologize again to the court
16 reporter.

17 Doctor, at the time that that event
18 occurs, is the zygote attached to the mother in
19 any way or is it floating just inside her body?

20 A. No. The placenta has not developed
21 yet or any attachment to the mother.

22 Q. So would it be fair to say that at

1 the time that Down's syndrome occurs, there is
2 no way any quantity of opioid on board the
3 mother would have any impact on that zygote?

4 A. That's correct.

5 Q. So would it then be fair to say that
6 given our understanding of biology as it exists
7 in 2020, that Down syndrome couldn't be related
8 to maternal opioid exposure?

9 A. Down's syndrome is not in any way
10 related to fetal opioid exposure.

11 MR. EHSAN: Thank you, Doctor. No
12 further questions.

13 Anything, Tom?

14 MR. BILEK: No. I am finished so we
15 can go home if everybody else is done. So
16 thank you for your time, Doctor.

17 MR. EHSAN: Thank you, Doctor. Be
18 safe.

19 (Whereupon, the proceeding was
20 concluded at 5:40 p.m.)
21
22

CERTIFICATE OF NOTARY PUBLIC

I, Bonnie L. Russo, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was duly sworn by me; that the testimony of said witness was taken by me in shorthand and thereafter reduced to computerized transcription under my direction; that said deposition is a true record of the testimony given by said witness; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this deposition was taken; and further, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of the action.

A handwritten signature in black ink, reading "Bonnie L. Russo", is written over a horizontal line.

Notary Public in and for
the District of Columbia

My Commission expires: August 30, 2024

Veritext Legal Solutions

1100 Superior Ave

Suite 1820

Cleveland, Ohio 44114

Phone: 216-523-1313

September 15, 2020

To: HOUMAN EHSAN

Case Name: National Prescription Opiate Litigation - NAS v.

Veritext Reference Number: 4242152

Witness: Lewis P. Rubin, M.D. Deposition Date: 9/10/2020

Dear Sir/Madam:

Enclosed please find a deposition transcript. Please have the witness review the transcript and note any changes or corrections on the included errata sheet, indicating the page, line number, change, and the reason for the change. Have the witness' signature notarized and forward the completed page(s) back to us at the Production address shown

above, or email to production-midwest@veritext.com.

If the errata is not returned within thirty days of your receipt of this letter, the reading and signing will be deemed waived.

Sincerely,

Production Department

NO NOTARY REQUIRED IN CA

DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 4242152

CASE NAME: National Prescription Opiate Litigation - NAS v.

DATE OF DEPOSITION: 9/10/2020

WITNESS' NAME: Lewis P. Rubin, M.D.

In accordance with the Rules of Civil
Procedure, I have read the entire transcript of
my testimony or it has been read to me.

I have made no changes to the testimony
as transcribed by the court reporter.

Date Lewis P. Rubin, M.D.

Sworn to and subscribed before me, a
Notary Public in and for the State and County,
the referenced witness did personally appear
and acknowledge that:

They have read the transcript;
They signed the foregoing Sworn
Statement; and
Their execution of this Statement is of
their free act and deed.

I have affixed my name and official seal

this _____ day of _____, 20____.

Notary Public

Commission Expiration Date

DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 4242152

CASE NAME: National Prescription Opiate Litigation - NAS v.

DATE OF DEPOSITION: 9/10/2020

WITNESS' NAME: Lewis P. Rubin, M.D.

In accordance with the Rules of Civil Procedure, I have read the entire transcript of my testimony or it has been read to me.

I have listed my changes on the attached Errata Sheet, listing page and line numbers as well as the reason(s) for the change(s).

I request that these changes be entered as part of the record of my testimony.

I have executed the Errata Sheet, as well as this Certificate, and request and authorize that both be appended to the transcript of my testimony and be incorporated therein.

Date

Lewis P. Rubin, M.D.

Sworn to and subscribed before me, a Notary Public in and for the State and County, the referenced witness did personally appear and acknowledge that:

They have read the transcript;
They have listed all of their corrections in the appended Errata Sheet;
They signed the foregoing Sworn Statement; and
Their execution of this Statement is of their free act and deed.

I have affixed my name and official seal
this _____ day of _____, 20____.

Notary Public

Commission Expiration Date

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

Veritext Legal Solutions is committed to maintaining the confidentiality of client and witness information, in accordance with the regulations promulgated under the Health Insurance Portability and Accountability Act (HIPAA), as amended with respect to protected health information and the Gramm-Leach-Bliley Act, as amended, with respect to Personally Identifiable Information (PII). Physical transcripts and exhibits are managed under strict facility and personnel access controls. Electronic files of documents are stored in encrypted form and are transmitted in an encrypted fashion to authenticated parties who are permitted to access the material. Our data is hosted in a Tier 4 SSAE 16 certified facility.

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